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FOOD SAFETY ENFORCEMENT AT THE LOCAL LEVEL  
IN FINLAND: RISK-BASIS, EFFICACY AND  
CONSISTENCY

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# ABSTRACT

Efficacious and consistent enforcement of food safety legislation is a cornerstone in protecting public health and preventing distorted competition between food business operators (FBOs). In case of non-compliance, food control authorities must provide the FBO with advice and requests to ensure that the FBO corrects the violation. If these actions do not induce compliance or the operations cause a health hazard, food control authorities are to employ stricter enforcement measures such as orders or prohibitions. Previous studies have revealed shortcomings in the use of enforcement measures, highlighting the need to investigate factors affecting their use. Moreover, understanding how FBOs perceive control actions is important for developing food control and promoting trust and positive perceptions of the quality and justness of control, thus improving food safety.

This thesis explores the risk-basis, efficacy and consistency of using administrative enforcement measures in local official food control in Finland. In addition, the importance and uniformity of local official food control are investigated from the perspective of FBOs in approved dairy, fishery and meat establishments. The methods include analysis of administrative enforcement decisions and inspection reports made by local authorities, survey and interview of local food control officials and survey of FBOs in approved dairy, fishery and meat establishments under local official food control.

Administrative enforcement measures are important control actions undertaken to force FBOs to correct multiple, recurrent or critical food safety violations. Food control officials have a risk-based approach to enforcement; the administrative enforcement process is initiated more rapidly and the duration of the process is shorter in critical than in non-critical food safety violations. The control actions are gradual, most often starting with a request and progressing to administrative enforcement measures in cases of non-compliance.

The use of administrative enforcement measures induces correction of non-compliances. However, local food control officials perceive the process as laborious and slow. The use of administrative enforcement measures is often preceded with repeated requests to correct non-compliances, and the duration of enforcement processes is often rather long. Recurrence of violations reveal recklessness of some FBOs towards food safety and deficiencies in the efficacy of enforcement.

The use of administrative enforcement measures varies among and within the local food control units. Some units have a strong routine and practical tools

available for using the measures, while others use them rarely or not at all. Unclear alignments and uncertainty in using administrative enforcement measures decrease the efficacy and consistency of enforcement. Many officials perceive the guidelines of the new disclosure system of inspection reports, the Oiva system, as helpful in enhancing the consistency of enforcement. Further efforts are nevertheless needed to establish the system and unify the interpretations.

Respondent FBOs in approved dairy, fishery and meat establishments consider official food control to be important for food safety and appear to be generally satisfied with its quality. However, many FBOs perceive the consistency of official food control as poor, and particularly small-sized FBOs are critical of the relevance of control actions. The Oiva system raises early-stage concerns among FBOs regarding the fairness and consistency of control. A perception of good co-operation with the official by FBOs is associated with their positive views about official food control and its importance.

The results of this thesis indicate that local food safety enforcement is generally risk-based and control actions are progressively adjusted. However, the speed, familiarity and consistency of using administrative enforcement measures could be improved. Provision of more practical training for officials and further development of operating instructions and peer-review systems between and within units would likely increase the efficacy and consistency of enforcement. Improving the consistency of control actions would also enhance the trust of FBOs in the relevance and justness of control.

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## LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following publications, which are referred to in the text by their Roman numerals:

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- III Kettunen, K., Pesonen S., Lundén, J., and Nevas, M. 2018. Consistency and risk-basis of using administrative enforcement measures in local food control. *Food Control* 85: 199-211.
- IV Kettunen, K., Lundén, J., Läikkö-Roto, T., and Nevas, M. 2017. Towards more consistent and effective food control: learning from the views of food business operators. *International Journal of Environmental Health Research* 27(3): 215-229.

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# ABBREVIATIONS

BSE	Bovine Spongiform Encephalopathy
COM	European Commission (Commission of the European Communities)
DG Sante	Directorate-General for Health and Food Safety
DVFA	Danish Veterinary and Food Administration
EC	European Communities
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EU	European Union
Evira	Finnish Food Safety Authority Evira
FAO	Food and Agriculture Organization of the United Nations
FBO	Food Business Operator
FSAI	Food Safety Authority of Ireland
FSA UK	Food Standards Agency of the United Kingdom
GHP	Good Hygiene Practices
HACCP	Hazard Analysis and Critical Control Points
MAF	Ministry of Agriculture and Forestry, Finland
OECD	Organisation for Economic Co-operation and Development
SME	Small- and medium-sized enterprise
SPSS	Statistical Package for the Social Sciences
UK	United Kingdom
US FDA	United States Food and Drug Administration
WHO	World Health Organization

# 1 INTRODUCTION

Food safety affects everyone. Food contaminated with pathogenic microbes or harmful chemical substances is estimated to cause illness for 600 million people each year, resulting in an annual loss of 33 million healthy life-years (World Health Organization [WHO], 2015). Ensuring that the basic need of safe food is met is a shared responsibility of food business operators (FBOs), the government and consumers (Käferstein, 2003).

The food field is among the most heavily regulated sectors in the European Union (EU) (van der Meulen, 2013). The key purposes of food safety legislation are to protect the health and interests of consumers by ensuring that food is safe, wholesome and traceable, and that the information provided about the food is truthful, sufficient and accurate (European Communities [EC], 2002; Ministry of Agriculture and Forestry [MAF], 2011b). In addition, food safety requirements aim at ensuring free and fair trade of food and improving the operating conditions for FBOs (EC, 2002; MAF, 2011b). In addition to food laws regulating the operations, agencies and effective methods for enforcement are required (Whitehead, 1995; Käferstein, 2003; Neeliah & Goburdhun, 2007). National food control systems often have limitations, such as obsolete food legislation, overlapping work, lack of resources and poor organization, weakening their efficacy (Food and Agriculture Organization of the United Nations [FAO] & WHO, 2003a; Neeliah & Goburdhun, 2007).

The current EU food safety legislation sets the primary legal responsibility for the safety of foodstuffs on FBOs at all stages of the food chain (EC, 2002). However, it is widely recognized that FBOs are not always able or willing to comply with the regulations (Henson & Heasman, 1998; Fairman & Yapp, 2004; Yapp & Fairman, 2006; Hirschauer et al., 2012). Official food control authorities therefore have the responsibility of ensuring that the FBOs have proper systems in place to manage the food safety risks in their operations and to comply with the legislative food safety requirements (EU, 2004d). In view of the costs of regulated food control, such as the costs of compliance for FBOs and the costs of administration and enforcement borne by FBOs and the government (Caswell, 1998; Henson & Heasman, 1998; Antle, 1999, 2000; Unnevehr & Jensen, 1999), it is important to conduct food control on a risk-basis and efficiently. Thus, identifying risk-based priorities and ensuring effective enforcement are core principles underlying EU food safety legislation (EC, 1999; EU, 2004d). At the same time, assuring consistency between and within the enforcement agencies is a major challenge in enforcement of food safety regulations (Ho, 2017).

The Finnish field of official food control has undergone changes with the introduction of the disclosure system of food inspection reports, 'Oiva', in 2013. Moreover, the prospective reform of the organization of local

environmental health and food control, bringing together the tasks of the current 62 local food control units into 18 counties, makes the development of official food control a highly topical issue. Strengthening the efficacy, risk-basis and consistency of control practices have been listed as objectives to improve the control of the Finnish food chain (Finnish Food Safety Authority Evira [Evira], 2015b, 2016e, 2017f).

In its broad concept, 'enforcement' covers all possible control actions applied by regulatory agencies and other law enforcement bodies aimed at ensuring and verifying compliance with laws, regulations and rules (Ayres & Braithwaite, 1992; Blanc, 2013). Enforcement actions range from guidance and education of the operators to inspections, testing and more coercive measures such as administrative procedures, sanctions and prosecutions (Blanc, 2013). In case of non-compliance, the EU food safety legislation obliges the competent authorities to take actions to ensure that the FBO remedies the situation (EU, 2004d). In Finland, these enforcement actions are defined in the Chapter 7 of the Food Act 23/2006 (MAF, 2011b) as administrative coercive measures. Improving efficacy in the use of administrative coercive measures is among the development objectives of official food control in Finland (Evira, 2017f), but scientific literature on this topic is scarce.

In this thesis, the term 'enforcement' is used to cover all actions of official control when the efficacy, risk-basis, consistency or other qualities of official controls are discussed. 'Enforcement measures', in turn, refer specifically to the administrative coercive measures available for Finnish food control authorities defined in the Chapter 7 of the Food Act (MAF, 2011b). Correspondingly, 'enforcement process' refers to the administrative procedure involved in using enforcement measures, i.e. the hearing procedure, administrative decision making and verification of compliance. 'Requests', by contrast, refer to non-administrative demands to correct non-compliances set by the food control authority or officials as defined in Section 53 of the Food Act (MAF, 2011b).

The term 'risk-basis' refers to the ability of food control authorities to adjust the control actions based on food safety risk caused by non-compliance, compliance history and level of own checks carried by the FBO (EU, 2004d). 'Efficacy' is used to describe the impact of official food control on food safety by assessing the correction of non-compliances and improvement of the level of food hygiene in food premises (Hampton, 2005; Lääkkö-Roto, 2016) as well as the promptness and fluency of the control procedures. 'Consistency' refers to the implementation of uniform principles and practices in enforcement within and between food control authorities in prioritization of enforcement approaches, use of control actions, adoption of national and internal guidelines and interpretation of the requirements set for FBOs (Lääkkö-Roto et al., 2015; Lääkkö-Roto, 2016; Tähkäpää, 2016).

'Food premises' refers to any company processing, selling, serving or distributing food. 'Approved establishment' or 'establishment' refers to a food premises handling, preparing or producing foodstuff of animal origin, such as

meat, fish and dairy products, that has to be approved in accordance with Regulation (EC) No 854/2004 and Regulation (EC) No 853/2004 (EU, 2004b, 2004c). Approved establishments attract specific regulatory attention because food of animal origin is a major vehicle for foodborne outbreaks (Gould et al., 2013; European Food Safety Authority [EFSA] & European Centre for Disease Prevention and Control [ECDC], 2016). As trust of FBOs in food control officials has been associated with their motivation to comply with food safety regulations (Yapp & Fairman, 2006; Meyer et al., 2017), understanding the factors affecting their attitude towards and perceptions of official food control is of particular importance.

The aim of this thesis was to evaluate food safety enforcement from two perspectives: by examining the views and control actions of food control officials and by exploring the perceptions of FBOs.

## 2 REVIEW OF THE LITERATURE

### 2.1 FOOD SAFETY AND PUBLIC HEALTH

#### 2.1.1 FOODBORNE ILLNESSES AND THE FOOD CHAIN

Food safety is an essential part of public health as food consumption influences the nutrition and health of all people. Although some traditional food-related infections, such as tuberculosis or typhoid fever, have been largely eradicated or controlled in industrialized countries (Tauxe & Esteban, 2006), foodborne illnesses remain a substantial global burden (Scallan et al., 2011; WHO, 2015; EFSA & ECDC, 2016).

Food is a potential vehicle for many infectious disease causative agents, including pathogenic bacteria, e.g. *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, *Escherichia coli* and *Clostridium perfringens* (McCabe-Sellers, & Beattie, 2004), viruses such as norovirus and hepatitis A and E (Koopmans et al., 2002; Koopmans & Duizer, 2004; Iturriza-Gomara & O'Brien, 2016) and protozoa such as *Cryptosporidium*, *Giardia* and *Toxoplasma* (Nichols, 2000; Dawson, 2005). In addition to microbiological food safety risks, acute illnesses or long-term diseases can be caused by chemical substances in food (WHO, 2015). These include, for instance, naturally occurring toxins such as mycotoxins, marine biotoxins and biogenic amines, food additives, environmental contaminants such as heavy metals, dioxins, pesticides and veterinary drug residues, and process contaminants like acrylamide (Alexander et al., 2012; Evira, 2014a; Ng & von Goetz, 2017). Among global food safety and public health risks, antimicrobial resistance is one of the most topical and urgent concerns (Marshall & Levy, 2011; Verraes et al., 2013; Roca et al., 2015; Ferri et al., 2017; EFSA & ECDC, 2018).

The annual global burden of foodborne illnesses is estimated to be 600 million illnesses and 420 000 deaths; in Europe, the annual burden is 23 million illnesses and 5000 deaths (WHO, 2015). In Finland, the reported foodborne outbreaks cause approximately 1500 illnesses annually (Evira, 2016c, 2017d). The most common vehicles for foodborne outbreaks in the EU as well as in the United States are animal origin foodstuffs: meat, poultry, dairy products and eggs (Gould et al., 2013; EFSA & ECDC, 2016).

Preventing foodborne outbreaks requires the united effort of all operators throughout the food supply chain: food processors, retailers, food service personnel and consumers (Tauxe, 2002; Käferstein, 2003; McCabe-Sellers & Beattie, 2004; Aruoma, 2006; Lupien, 2007). The globalization of the food trade and the increasing complexity of food supply networks pose challenges for prevention of foodborne illnesses (Robertson et al., 2003; Flint et al., 2005; Raspor, 2008; Tauxe et al., 2010). Through the wide distribution of foodstuffs, possible health hazards at the production level may affect large populations,



not only locally but also globally (Tauxe et al., 2010). In the EU, the food chain employs more than 47 million persons in over 15 million companies engaged in primary production, the food processing industry or food retail or services (European Commission [COM], 2015). In Finland, the entire food chain employs a total of 300 000 people (Hyrylä, 2016), and the number of food premises under official food control of is over 75 000 (Evira, 2016e).

### **2.1.2 FOOD SAFETY RISK FACTORS IN FOOD PREMISES**

Recognized, reported and investigated outbreaks represent only the peak of the iceberg regarding actual outbreaks (WHO, 2008, 2015; Greig & Ravel, 2009; Gould et al., 2013). Most reported foodborne outbreaks derive from places in which food is consumed or prepared for consumption, such as restaurants, workplace catering or households (Gould et al., 2013; EFSA & ECDC, 2016), probably because the traceability of the source of illness of several people eating at the same place is easier than that of individual or sporadic cases occurring in different places (McCabe-Sellers & Beattie, 2004). Food can become contaminated during any stage of the food chain, and unless the survival and/or growth of pathogens is controlled during food processing the risk of an illness derived from food increases (Nyachuba, 2010). Inabilities to control certain factors related to the operations or the working practices of food handling personnel of food premises are especially reported to be associated with the occurrence of foodborne outbreaks (Buchholz et al., 2002; Gormley et al., 2011; United States Food and Drug Administration [US FDA], 2013; EFSA & ECDC, 2016). These critical food safety factors include use of clean water and raw materials from safe sources, appropriate temperature control during preparation and storage of food, prevention of cross-contamination between raw and cooked foods, and proper personal and hand hygiene of food handlers (Buchholz et al., 2002; US FDA, 2013; Gormley et al., 2011; EFSA & ECDC, 2016). Improper temperature control is the main contributing factor to reported foodborne outbreaks (Todd, 1997; Olsen et al., 2000), and violations of temperature control have been described to increase the likelihood of a restaurant being a source of an outbreak (Irwin et al., 1989). Hand hygiene has been noted to have a significant role in, for example, transmission of noroviruses (Barrabeig et al., 2010; Rönnqvist et al., 2014; Boxman et al., 2015) and outbreaks caused by Salmonella (Kimura et al., 2005; Medus et al., 2006).

Despite their importance for prevention of foodborne outbreaks, violations of critical food safety factors are relatively commonly observed during routine inspections of food premises (Phillips et al., 2006; Reske et al., 2007; Guiducci et al., 2011). Recent studies have reported an absence of temperature storage records in 34% of catering service kitchens (Garayoa et al., 2017) and temperature violations in 50% of food products in retail stores (Lundén et al., 2014b). Temperature violations have also been noted among the most common reasons behind the use of enforcement measures (Lundén, 2013).

Unsatisfactory hygienic working practices and deficient prevention of cross-contamination are also rather frequently reported among food handlers (Baş et al., 2006; Kwon et al., 2014; Garayoa et al., 2017).

## **2.2 FOOD SAFETY REGULATION CONCERNING FOOD PREMISES**

### **2.2.1 PRINCIPAL OBJECTIVES AND DEVELOPMENT OF FOOD SAFETY LEGISLATION**

Food law and regulations build a foundation for a food control system (Whitehead, 1995). The principal objectives of food safety legislation and control systems are to protect the health and interests of consumers by ensuring the safety and traceability of food and that the information given about food is truthful and sufficient (EC, 2002; MAF, 2011b). In addition, food safety requirements aim at facilitating the trade of food and improving the operating conditions for FBOs (EC, 2002; MAF, 2011b). The primary legal responsibility for ensuring food safety lays with FBOs (COM, 1999; EC, 2002). Official control systems established at both national and EU levels have the responsibility of enforcing the legislation and ensuring the compliance of FBOs (COM, 1999; EU, 2004d).

Setting rules for the sale of food to protect people from adulterated or poor-quality food have been a goal of governing authorities since the earliest documented eras of human history (FAO & WHO, 2016). International harmonized standards facilitating the trade of safe foods started to take place in the early 20th century, and the current global food safety legislation was founded in 1963, when FAO and WHO established the Codex Alimentarius (Codex) or "Food Code" (FAO & WHO, 2016). Codex is a set of food standards, codes of practice and guidelines aiming at harmonized international food standards to protect consumer health and promote fair practices in international food trade. Today, the Codex Commission consists of 188 member countries, covering 99% of the world's population; the EU is a member organisation. The Codex standards, produced and updated based on scientific evidence, are recommendations for voluntary compliance by members, but in many governments and non-governmental organizations, they serve as a basis for legislation and regulations (FAO & WHO, 2016).

Major food safety or fraud crises in recent decades, such as "mad cow disease" (Bovine Spongiform Encephalopathy, BSE) in the United Kingdom (UK) in 1996, dioxins in feed in Belgium in 1999, melamine in Chinese milk in 2008 and the horse meat scandal in Europe in 2013, have made food safety a "hot" topic in politics and in the media and among consumers (Raspor, 2008; Newell et al., 2010; Aung & Chang, 2014; Bánáti, 2014; Barnett et al., 2016). In addition, the crises have challenged the credibility of the food industry and

led to demands for more effective, risk-based, consistent and transparent food safety regulation, standards and controls (Vos, 2000; Aung & Chang, 2014). As a consequence of the BSE crisis revealing serious shortcomings in the existing European food law, EU food safety regulations were changed from an *ad hoc* principle to a more precautionary and integrated approach to food safety (Vos, 2000; Caduff & Bernauer, 2006; Halkier & Holm, 2006; van der Meulen, 2013). In its White Paper on Food Safety in January 2000 (COM, 1999), the European Commission declared the objective of the future development of European food safety law. The principles proclaimed as being fundamental for public health protection policy – scientific advice as a basis for all regulatory activities, risk assessment in identifying control priorities, and greater transparency in decision-making and control – set the foundation for a new food safety approach (COM, 1999). The aim was to guarantee a high level of food safety by creating a new legal framework covering all sectors of the food chain from farm to fork, including feed production, primary production, food processing, storage, distribution and retail sale (COM, 1999).

In parallel to the public regulatory response to the demand for more effective food safety controls and the shift of legislative responsibility of food safety towards FBOs, the collaboration between the public and private food sectors has increasingly evolved (Garcia Martinez et al., 2007; Garcia Martinez et al., 2013; Rouviere & Royer, 2017). The basic principle in the collaborative regulatory strategy involving public and private partnership in the food safety field, commonly termed ‘co-regulation’ (Garcia Martinez et al., 2007, 2013) or ‘enforced self-regulation’ (Fairman & Yapp, 2005), is that the government imposes requirements on FBOs to develop and implement their own risk management systems to ensure, monitor and verify compliance with the regulations (Fairman & Yapp, 2005; Garcia Martinez et al., 2007; Hutter & Amodu, 2008). To respond to the challenges of an internationalized food chain and increased consumer demands, the food industry has also increasingly adopted private quality assurance and standard systems on top of the legislative requirements (Trienekens & Zuurbier, 2008; Garcia Martinez et al., 2013).

### **2.2.2 GENERAL FOOD SAFETY LEGISLATION**

The EU food safety legislation is based on the requirements of the Codex standards (Poli, 2004). Regulation (EC) No 178/2002, or “General Food Law”, is the foundation of EU food and feed law (EC, 2002). It lays down the general principles and requirements of food and feed safety law, covering all stages of the food chain. According to the General Food Law, only safe food can be placed on the EU market, and food is deemed safe if it complies with the basic criteria established in law. When food is unsafe, FBOs are obliged to withdraw or recall it from the market and to carry out other measures required by the competent national authority to ensure that the food safety risk is reduced or eliminated (EC, 2002).

To complement the EU legislation, member states may also have their own national legislation with respect to food safety, provided that this is not in conflict with the requirements set out by the EU legislation. The adoption of EU directives into national rules can, however, vary considerably between member states due to differing national legal systems and political and administrative actors (Steunenbergh, 2006). In Finland, the national food safety legislation is built around Food Act 23/2006 (MAF, 2011b), which lays down the general requirements concerning food premises, the handling, storing and transportation of food, own-check plan, food hygiene competence of food handlers, and notification of food premises and application for approval as a food establishment (MAF, 2011b).

### **2.2.3 LEGISLATION ON HYGIENE IN FOOD PREMISES**

Effective food safety risk management from farm to fork during handling, storing, preparing and serving of food is the basis for reducing the risk of foodborne illnesses. The general requirements for the hygiene of foodstuffs and hygienic handling of food are laid down in Regulation (EC) No 852/2004 (EU, 2004a). The regulation applies to all foodstuff and all FBOs from farm to fork and contains general obligations for the hygiene of food handling, premises and equipment, personal hygiene and training, and temperature processes (EU, 2004a). The structure and wording of the legislation allow flexible and relative application of the rules.

Regulation (EC) No 852/2004 lays down the requirements for implementing good hygiene practices (GHP) and Hazard Analysis and Critical Control Points (HACCP) -based food safety management procedures (EU, 2004a). Originally developed by the American space agency NASA to ensure that astronauts would not suffer from foodborne illnesses during their stay in space, HACCP is a system that identifies, evaluates and controls the physical, chemical and biological hazards in the operations that could endanger food safety (FAO & WHO, 2003b; van der Meulen, 2013). HACCP principles have been adopted in the Codex Alimentarius standards as a food safety management system worldwide (FAO & WHO, 2003b; van der Meulen, 2013). In the EU legislation, the requirements to establish and maintain food safety programmes and procedures based on the HACCP principles apply to all FBOs, with the exception of primary production (EU, 2004a). If identification or monitoring of critical control points is not possible, GHP can replace them in certain operations (EU, 2004a).

Due to the frequently reported health hazards presented by foodstuffs of animal origin (Gould et al. 2013; EFSA & ECDC, 2016), their production and placing on the market are considered to require specific hygiene rules, which are laid down in Regulation (EC) No 853/2004 (EU, 2004b). According to this regulation, establishments handling foodstuffs of animal origin, e.g. meat, fishery products, milk and dairy products, shall not operate unless approved by the competent authority. The regulation sets detailed requirements for the

structural, operational and hygiene requirements for the establishments; temperature requirements during storage and transport of foodstuffs; and health and identification marking of foodstuffs (EU, 2004b).

In addition to regulations regarding operations and hygiene in food premises, EU legislation lays down some specific requirements, for instance, for the provision of food information to consumers (EU, 2011) and microbiological criteria for foods regarding certain micro-organisms (EU, 2005). The regulation on food information prescribes detailed requirements for the accuracy and truthfulness of the information given on food, in particular food labelling, regarding the identity, composition, properties or other characteristics of the food (EU, 2011).

To complement the requirements set in the EU food hygiene regulations, Finland has national legislation on food hygiene and safety. The Finnish Decree of the Ministry of Agriculture and Forestry on food hygiene in registered food premises 1367/2011 and the Decree of the Ministry of Agriculture and Forestry on food hygiene in approved food establishments 795/2014 lay down more detailed structural and operational requirements for the facilities, and requirements on the temperature of the food during processing, storage and transport, on the hygienic work routines of personnel, and on in-house control and its documentation by FBOs (MAF, 2011a, 2014a). The Decree of the Ministry of Agriculture and Forestry 834/2014 sets requirements on packed and unpacked foodstuff delivered to consumers regarding the language of the labelling, marking of the batch number of the food and information given on allergenic substances (MAF, 2014b).

## **2.3 COMPLIANCE IN FOOD BUSINESS**

### **2.3.1 MOTIVATION TO COMPLY**

The compliance process in food business, as described by Henson and Heasman (1998), is a cycle of decision-making activities, during which the company chooses whether and when to comply with a regulation and the actions taken to reach compliance. Furthermore, the company evaluates the outcome of the compliance strategy and adjusts its activities accordingly (Henson & Heasman, 1998). The decisions concerning what has to be done to comply depend on the type and administrative form of the regulation; for instance, regulations regarding specific temperature requirements are rather clear, whereas a requirement to implement good hygiene practices allows broader interpretation (Henson & Heasman, 1998).

In addition to the incentives set by the regulatory requirements (Hammoudi et al., 2009; Mensah & Julien, 2011), motivational factors to implement food safety management systems include e.g. product safety and quality improvements, customer requirements and consumer awareness

(Mensah & Julien, 2011; Fernando et al., 2014). The costs of non-compliance, such as economic losses due to possible fines, recalls and withdrawals of the foodstuffs from the market or cessation of operations, also encourage FBOs to comply with the food safety requirements (Hammoudi et al., 2009). Fairman and Yapp (2004) concluded that the compliance decision-making process may not be made internally and independently, but the motivation to comply is influenced by external factors such as encounters with enforcement officers or trade association information.

### **2.3.2 CHALLENGES OF FBOS TO MANAGE FOOD SAFETY RISKS AND COMPLY WITH LEGISLATIVE REQUIREMENTS**

Financial, infrastructural and people-related constraints of FBOs to implement food safety management system and comply with food safety regulations are widely reported in scientific literature (Table 1). The propensity of a food business company to adopt food safety practices are associated by several characteristics of the company such as the size, industry subsector, the country of ownership and control, level of innovativeness and export orientation and forms of regulatory food safety inspections (Herath et al., 2007). Moreover, several authors emphasize the role of the food safety culture of the company in building the basis for food safety management and promoting hygienic practices (Clayton & Griffith, 2008; Griffith et al., 2010a; Powell et al., 2011; Strohbahn et al., 2014). According to Griffith et al. (2010b), the “cultural” factors contributing to food safety performance could include food safety management systems, food safety commitment, food safety environment, risk perception, leadership, and communication. Other authors note the importance of a suitable working environment and qualified, committed and motivated personnel for a functioning HACCP system (Jevšnik et al., 2008b; Fotopoulos et al., 2009). A recent study in the UK concludes that implementing food safety culture has a broad potential and support among food safety stakeholders, but the tools used for assessing food safety culture in food businesses should be further developed (Nayak & Waterson, 2017).

**Table 1.** *Commonly reported hurdles, difficulties or deficiencies among FBOs to comply with food safety regulations or implement food safety management systems.*

Hurdle to compliance	Reference
Lack of knowledge or understanding of food safety management or the legislative requirements	Walker et al., 2003a, 2003b; Fairman & Yapp, 2004; Yapp & Fairman, 2006; Baş et al., 2007; Violaris et al., 2008; Fotopoulos et al., 2011; Mensah & Julien, 2011; Karaman, 2012; Karaman et al., 2012; Lundén et al., 2014b; Smigic et al., 2016
Financial hurdles or fear of increase of costs	Fairman & Yapp, 2004; Eves & Dervisi, 2005; Yapp & Fairman, 2006; Violaris et al., 2008; Mensah & Julien, 2011; Karaman et al., 2012; Nevas et al., 2013; Wengle, 2015
Lack of personnel, facilities or time to implement food safety management systems	Panisello & Quantick, 2001; Eves & Dervisi, 2005; Yapp & Fairman, 2006; Baş et al., 2007; Mensah & Julien, 2011; Nevas et al., 2013; Luning et al., 2015; Wengle, 2015
Lack of motivation or interest towards or poor commitment to food safety management systems	Panisello & Quantick, 2001; Eves & Dervisi, 2005; Yapp & Fairman, 2006; Baş et al., 2007; Fotopoulos et al., 2011
Lack of trust in food safety legislation and food control officials	Yapp & Fairman, 2006; Meyer et al., 2017
Limited ability to identify hazards and take into account the risks involved in the operations	Panisello et al., 1999; Eves & Dervisi, 2005; Fielding et al., 2005; Nevas et al., 2013
Lack of manager or organizational contribution supportive of maintaining safe food handling practices or implementing HACCP	Pragle et al., 2007; Bánáti & Lakner, 2012

A particular challenge appears to be ensuring adequate expertise in food safety requirements. For instance, the detected discrepancies between the own-checking records of retail FBOs and observations made during official inspections (Lundén et al., 2014a) indicate that some FBOs have inadequate ability to ensure proper temperatures of the foodstuffs with their in-house control. Moreover, as reported by Haukijärvi and Lundén (2017), waiving of pre-inspections and pre-approvals of restaurants has weakened the compliance concerning the infrastructure of the premises relative to the time when pre-approval was needed before initiation of operations, indicating that

FBOs may have deficient knowledge of the requirements of food premises and preconditions of GHPs.

To strengthen the knowledge of food handlers and to promote their positive attitudes towards food hygiene, education and training appear beneficial (Abdul-Mutalib et al., 2012; Ko, 2013; McIntyre et al., 2013; Lääkkö-Roto & Nevas, 2014b; Baser et al., 2017). However, conclusions drawn by other studies on the effectiveness of food handler training programmes and certification in improving the knowledge and hygienic practices of food handlers are conflicting, and several authors argue that an increase in the knowledge and awareness of hygienic practices may not automatically lead to changes in the behaviour of food handlers (Ehiri & Morris, 1996; Ehiri et al., 1997; Clayton et al., 2002; Seaman & Eves, 2010a). Thus, many studies highlight the importance of an organizational contribution and manager support to achieve and maintain a culture supportive for safe food handling behaviour and hygienic practices (Ehiri et al., 1997; Clayton et al., 2002; Mitchell et al., 2007; Seaman & Eves, 2010b; Strohbahn et al., 2014; Smigic et al., 2016).

#### ***2.3.2.1 Special challenges of establishments producing food of animal origin***

Establishments producing food of animal origin may face several challenges to meet the extensive legislative requirements (Hielm et al., 2006; Kotisalo & Nevas, 2009; Tähkäpää et al., 2009a; Karaman, 2012; Karaman et al., 2012; Nevas et al., 2013). In a study on European companies producing food of animal origin, Luning et al. (2015) reported that most companies have adequate food safety management systems, but activities related to verification and validation of the control systems appear to be more challenging. According to Finnish studies, the attitudes of employees of approved establishments towards the HACCP and in-house control systems are very positive (Hielm et al., 2006), but their implementation is more problematic (Tähkäpää et al., 2009a). Choosing the critical control points, committing all employees of the company to the system and documenting the monitoring results are considered particularly difficult (Hielm et al., 2006), and many FBOs wish for more guidance with planning the self-checking system (Nevas et al., 2013).

In addition to HACCP and in-house control systems, the requirements seen as most problematic by the Finnish FBOs of approved establishments have been associated with the layout of the premises and transport routes, structure and maintenance of premises, control fees and labelling (Tähkäpää et al., 2009a). Lacking or poor organization of premises and inadequate maintenance have been reported as the most common non-compliances among fishery and meat establishments (Kotisalo & Nevas, 2009). Moreover, particularly FBOs in meat and fish sectors have experienced the correction of non-compliances as financially difficult (Nevas et al., 2013) and have had



multiple and often serious non-compliances that have led to the use of administrative enforcement measures by control authorities (Lundén, 2013). Moreover, Tähkää et al. (2009a) reported that meat and fish business operators perceive differing interpretations of the requirements by the control authorities as problematic.

### **2.3.2.2 Special challenges of small FBOs**

One of the core factors explaining differences in compliance among individual companies is the size of the company (Henson & Heasman, 1998; Fairman & Yapp, 2004). Based on the categorization by the Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises (SMEs), as based on their number of employees, annual turnover, and/or annual balance sheet (COM, 2003), up to 99% of the companies in EU food and drink industry are SMEs (FoodDrinkEurope, 2016). In Finland, 75% of the food industry is micro-companies employing less than 10 persons (Hyrylä, 2016). The classification of company sizes varies in the scientific literature, but several studies conclude that smaller companies often have particular difficulties in complying with food safety requirements or implementing food safety management systems (Panisello et al., 1999; Taylor, 2001; Walker et al., 2003b; Fairman & Yapp, 2004; Fielding et al. 2005; Yapp & Fairman, 2006; Violaris et al., 2008; Tähkää, Kaario et al., 2009; Wilcock et al., 2011). Smaller FBOs may not perceive ensuring compliance with food safety regulations as a part of their operations, but rather as an outcome that is achieved when the requirements stated by the enforcement official are fulfilled (Fairman & Yapp, 2005; Yapp & Fairman, 2006). Also Taylor and Kane (2005) reported that smaller FBOs see the HACCP system as difficult and with hardly any benefits. Moreover, due to their possibly limited resources and capabilities, smaller FBOs presumably consider the burden of maintaining compliance and implementing food safety management systems as heavier than larger companies (Jayasinghe-Mudalige & Henson, 2007; Mensah & Julien, 2011; Wengle, 2015), thus being less likely to implement HACCP or other enhanced food safety assurance systems (Panisello et al., 1999; Herath et al., 2007). In a Spanish study, hygiene practices in small- and medium-sized retail food premises were reported to be indeed poorer than in large-sized FBOs (Pérez-Rodríguez et al., 2010). However, guidance and support can help smaller FBOs to improve implementation of food safety management systems (Taylor & Kane, 2005; Luning et al., 2015).

## **2.4 OFFICIAL FOOD CONTROL**

### **2.4.1 LEGISLATION FOR OFFICIAL FOOD CONTROL**

Realization of rules and regulations requires effective enforcement and ensuring compliance with the requirements (Blanc, 2013; WHO, 2013; Organisation for Economic Co-operation and Development [OECD], 2014). A well-functioning official food control system is essential for protecting public health (WHO, 2013; OECD, 2014), and it promotes the competitiveness of the FBOs by preventing distorted competition between compliant and non-compliant FBOs (Hampton, 2005). The legislative framework, available measures and procedures of enforcement vary among countries, but generally, official food control covers all mandatory regulatory enforcement activities by national or local authorities necessary to protect the consumers by ensuring the quality and safety of food during all stages of the food chain (FAO & WHO, 2003a).

In the EU, enforcement of food safety legislation is the responsibility of member states, which must maintain a system of official controls to monitor and verify that the FBOs fulfil the legislative requirements at all stages of the food chain (EC, 2002; EU, 2004d). The requirements for official food controls in the EU are set in Regulation (EC) No 882/2004 (EU, 2004d), and Regulation (EC) No 854/2004 lays down specific rules for the organization of official controls for products of animal origin intended for human consumption (EU, 2004c). Official control shall be impartial, consistent and of high quality (EU, 2004d). The controls shall be carried out regularly, on a risk basis and with appropriate frequency (EU, 2004d). The competent authority shall ensure that it has an adequate number of qualified and experienced staff to perform official controls effectively (EU, 2004d). The Directorate-General for Health and Food Safety (DG Sante) carries out audits, inspections and related non-audit activities to ensure that the national authorities fulfil their legislative obligations and that EU rules are complied with in all member states (COM, 2017).

### **2.4.2 ORGANIZATION OF OFFICIAL FOOD CONTROL IN FINLAND**

The competent food control authorities, their duties and available control measures are defined in the Finnish Food Act (MAF, 2011b). Official food control is organized at three levels: locally, regionally and nationally. Most practical food control tasks are conducted at the local level in control units (henceforth “units”) formed of the municipal cooperation areas of environmental health and food control that consist of one or more municipalities (Ministry of Social Affairs and Health, 2009; MAF, 2011b). Since the beginning of 2015, the number of units is 62 (Evira, 2015b, 2017f). The units operate under municipal authority bodies, which are multimember bodies named by the municipalities within the control unit (MAF, 2011b).

Within their areas, each unit independently plans and implements the official food control tasks laid down in the EU food safety regulations and the Finnish Food Act (MAF, 2011b). Annually, the human resources designated for food safety control are approximately 718 labour-years, 253 of which are in the municipal food control units (Evira, 2017f). The head of the unit is often a veterinarian (Aas et al., 2004).

Regionally, the units are guided by six Regional State Administrative Agencies that, within their areas of operation, direct and assess the performance of the municipal food control units (MAF, 2011b). Under the auspices of and national legislation drawn by the MAF, Evira coordinates, leads and develops nationwide food control and gives national guidelines on hygiene and regulations concerning food and in-house control by FBOs (MAF, 2011b). Evira is also responsible for meat inspection and official food control in slaughterhouses and supervising or performing the control of the foodstuff of animal origin delivered to Finland from other EU member states (MAF, 2011b).

Other national food control authorities are the Finnish Customs and the Finnish Defence Forces. Finnish Customs is responsible for the control of foodstuffs other than animal origin imported to Finland from third party countries. The Defence Forces supervises the safety and compliance of foodstuffs in its own areas (MAF, 2011b).

#### **2.4.2.1 Resources and performance of local food control units**

The municipal independence, safeguarded in the Constitution of Finland (Ministry of Justice, 2011), may generate certain dissimilarities in conducting official food control tasks in local food control units, possibly setting FBOs in unequal positions depending to the location of their company (Tähkää et al., 2008; Tähkää et al., 2009b). Ensuring adequate labour resources and their optimal allocation are ongoing issues in local food control (Tähkää et al., 2008; Evira, 2014b, 2015b, 2017f; Lääkkö-Roto et al., 2016). Several studies have reported variation among the units in resourcing of food control, in collecting control fees from FBOs and in risk-based approach (Tähkää et al., 2008; Tähkää et al., 2009b; Lepistö et al., 2010; Heikkilä et al., 2016). As stated by Tähkää et al. (2008), weak knowledge of food control among municipal decision-makers and a low appreciation of the field of environmental health control are the most critical reasons for the lack of resources in local food control.

Insufficient resources have been associated with inadequate implementation of local food control plans (Evira, 2014b, 2015b). Lääkkö-Roto et al. (2016) reported that less than one-third of the heads of the units consider that restaurant inspections occur regularly and sufficiently in their units. Moreover, approximately one-third of the units consider their resources to be inadequate for providing guidance to FBOs (Evira, 2015b). The efficacy and appropriateness of official food control implemented by local food control are

evaluated by the Regional State Administrative Agencies (MAF, 2011b). The local food control officials have not, however, perceived the audits to be very useful and have been dissatisfied with the expertise of the regional officials performing the audits (Läikkö-Roto & Nevas, 2014a). Moreover, the evaluation results have not been sufficiently utilized in guiding and developing official food control (Läikkö-Roto & Nevas, 2014a).

Despite the challenges related to resources and consistency of practices, the units appear to be capable of ensuring adequate facilities and equipment for conducting official food control tasks (Läikkö-Roto et al, 2016). Guidance papers, pre forma templates and possibilities to hold collective discussions about the control cases within the unit have been reported to be important for the quality and efficacy of control (Läikkö-Roto et al, 2016). However, incomplete commitment to and familiarization with the operating procedures, quality systems and templates of their unit among the officials, poor orientation of the personnel and existence of tacit knowledge have been defined as factors potentially weakening the quality and efficacy of control (Läikkö-Roto et al., 2016). Moreover, experienced negative work stress among officials and their insufficient abilities to allocate work hours to become familiar with new legislation and guidelines may decrease employee performance and quality of work (Läikkö-Roto et al., 2016). Management skills of the heads of the units are thus considered fundamental for the units to conduct high-quality controls (Läikkö-Roto et al., 2016).

#### ***2.4.2.2 Prospective reform in organization of official food control***

Several recent reports have investigated different possibilities to organize official food control in Finland (Hirn, 2011; Nevas & Lepistö, 2015; Tarasti, 2016). Hirn (2011) concluded that the organization of environmental health and food control is multi-tier both horizontally and vertically, causing the system to be expensive, heavy and ineffective and leading to ambiguity among jurisdictions and inequality both regionally and locally (Hirn, 2011). According to Nevas and Lepistö (2015), the primary needs entail developing the central guidance system and establishing a joint database for reporting the control data, but the size of the units could be increased by forming larger regional units and allocating the resources of the Regional State Administrative Agencies to practical control tasks. Tähkää et al. (2008) have, however, already earlier expressed their concerns related to larger control units. In larger units, the possibilities for the officials to specialize in certain areas and improve their expertise likely increase. However, the decision-making covering larger entities and the decision-makers being farther away from the practical work and the personnel could weaken their knowledge and appreciation of the field, thus resulting in less funding and resources (Tähkää et al., 2008). On the other hand, according to Kotisalo et al. (2015), centralization of meat inspection tasks has standardized meat inspection fees

and improved the guidance provided by the central authority to official veterinarians.

A major reform is anticipated in environmental health and food control at the beginning of 2020. On the basis of suggestions made by Tarasti (2016), the environmental health and food control tasks of municipal units will be brought together into 18 counties (Government of Finland, 2017a, 2018). With respect to food control, the reform aims at reducing administrative levels in control and supervision, improving the consistency and cost efficacy of control and creating better possibilities for specialization and expertise (Government of Finland, 2017a). If a municipality has adequate resources, it could organize certain environmental health control tasks on its own (Government of Finland, 2017a, 2017b).

## **2.5 REQUIREMENTS FOR ENFORCEMENT**

### **2.5.1 RISK-BASIS OF ENFORCEMENT**

The demand for risk-based regulation and enforcement arises from the need to target scarce public resources, to reduce the administrative burden on regulated business and to improve efficacy of enforcement (Black, 2005; Hampton, 2005, Garcia Martinez et al., 2013; OECD, 2014). The EU food safety legislation states that the control activities should be based on risks (EU, 2004a, 2004d), while simultaneously allowing national or even local interpretation (van Asselt et al., 2012). The implementation of risk-based control comprises risk categorization and defining the frequency of controls accordingly (van Asselt et al., 2012), resulting in the FBOs with the highest risk bearing most of the burden of enforcement (Hampton, 2005). According to the General Food Law, 'risk' refers to the probability and severity of an adverse health effect caused by a hazard, whereas 'hazard' refers to a biological, chemical or physical agent in, or condition of, a food that potentially may cause an adverse health effect (EC, 2002). In defining the need and frequency of official food safety controls, the risks involved in a food business are determined on the basis of the nature and extent of the operations and the foodstuff produced, the results and reliability of the own checks and the compliance history of the FBO (EU, 2004d; Evira, 2017b). For instance, manufacturing large quantities of ready-to-eat foods from animal-origin raw ingredients requiring controlled temperature conditions poses a greater risk than small-scale retail selling of packed dry food at room temperature, thus warranting more frequent and time-consuming inspections (Evira, 2017b). Furthermore, the inspection frequency of an FBO with several excellent inspection results can be reduced, whereas non-compliances observed during inspections result in additional inspections (Evira, 2017b).

Risk should be considered at all levels of the decision-making involved in regulatory enforcement – from allocation of resources to proportionate enforcement approaches and sanctioning actions (FAO, 2008; OECD, 2014). Ensuring the use of a consistent definition of risk by all control authorities is essential (OECD, 2014). However, the qualitative risk assessment involved in food safety regulation allowing flexibility and discretion critically relies on the expertise and experience of the control officials making the subjective judgments (Black & Baldwin, 2010). According to a Finnish study, food control officials appear to implement a risk-based approach and relativity in practice by taking the compliance history of an FBO into account in determining inspection frequencies and strictness of control actions (Läikkö-Roto et al., 2015). However, “evaluation of food hygiene and operational hygiene” and “evaluation of the severity of neglecting legislative requirements, and needed control actions” were considered to be among the most necessary training areas by the officials (Läikkö-Roto et al., 2015).

## **2.5.2 EFFICACY OF ENFORCEMENT**

The efficacy of official food control can be assessed by analysing the impact of official food control on the hygiene of a food premises, the role of inspections in detecting non-compliances and the ability of control actions to ensure that the non-compliances are corrected (Läikkö-Roto & Nevas, 2014b; Läikkö-Roto et al., 2015; Läikkö-Roto, 2016). Furthermore, effective enforcement involves the ability of authorities to simply and effectively communicate their requirements to FBOs, thus increasing awareness and understanding of FBOs regarding the regulations (Hampton, 2005). The efficacy or cost-efficiency of enforcement can be assessed through the ability of controls to conduct efficacious interventions and achieve the desired aim – compliance – with a minimum waste of resources of authorities, such as money, time or effort (Hampton, 2005; Läikkö-Roto, 2016), and without an excessive administrative burden on FBOs (Hampton, 2005).

Adoption of the variety of available enforcement tools, from educational approach to formal actions, is an essential part of efficacious food safety enforcement (Yapp & Fairman, 2006). Efficacy of enforcement can be assessed on the basis of the control authorities being able to, on one hand, penalize persistent non-compliers, and on the other hand, reward compliant performance by FBOs (Hampton, 2005). Adequately deterrent effect of penalties prevents the most negligent FBOs from offending the regulations (Hampton, 2005) and may help consumers feel confident about the safety of the food supply chain and its control (Barnett et al., 2016). However, the enforcement methods and sanctions employed differ between EU member states: for instance, cases of food fraud are seldom taken to court in Finland, whereas FBOs are prosecuted for similar offences in the UK (Tähkäpää et al., 2015; Tähkäpää, 2016). Moreover, the observed negligence by Finnish FBOs towards the instructions and orders given by control officials indicate that the

control measures used may not be sufficiently rapid or efficacious to prevent repeated violations (Tähkää et al., 2015; Tähkää, 2016). Also Lepistö (2008) concluded that if stricter control measures are not adequately used and food safety offences remain unreported to the police, no case law or homogeneous convention of penalties is formed, leading to diminished efficacy of regulations and control measures. Unequal treatment of FBOs and recurrence of violations may enable distortion of competition between FBOs and jeopardize public health (Tähkää, 2016).

### **2.5.3 UNIFORMITY AND CONSISTENCY OF ENFORCEMENT**

Equality is a basic legal right and a fundamental principle of good governance (Ministry of Justice, 2003, 2011; COM, 2012). FBOs shall thus be treated on an equal basis and the acts of the food control authority shall be impartial and proportionate to their objective (Ministry of Justice, 2003; EU, 2004d). However, the national-level implementation and enforcement of EU food hygiene legislation varies between member states (Havinga, 2014). Thus, perceived or actual inconsistency is a common challenge in official food control and enforcement practices within and between local control authorities (e.g. Fairman & Yapp, 2005; Hutter & Amodu, 2009; Mascini & Wijk, 2009; Pham et al., 2010a; Ho, 2012, 2017; Lee-Woolf et al., 2015; Meyer et al., 2017). A Finnish study reports that only 7% of local food control officials conducting restaurant inspections consider official food control to be uniform throughout the country (Läikkö-Roto et al., 2015).

Characteristics of the local authority, such as size, resources and location, have been reported to affect enforcement practices (Hutter & Amodu, 2009; Läikkö-Roto et al., 2015). Also legislative food safety requirements that allow flexible interpretation and are enforced at the discretion of authorities may be problematic from the viewpoint of consistent treatment of FBOs and cause inconsistency in the regulatory outcomes (Hutter & Amodu, 2009). Inconsistency among inspecting officials as well as between local food control units has been reported in inspection practices, documentation of observed non-compliances and issuing of demands for their correction (Läikkö-Roto et al., 2015). Differences among inspectors have been reported to affect the detection of violations and scoring of inspections (Lee et al., 2012) and the selection of enforcement methods in non-compliance cases (Mascini & Wijk, 2009; Johnson et al., 2014; Läikkö-Roto et al., 2015). To improve consistency of control, many scholars recommend standardized inspection schemes and regular retraining of inspectors on violation assessment (Jones et al., 2004; Lee et al. 2012; Läikkö-Roto et al., 2015) as well as peer review among officials (Ho, 2017).

## 2.6 ENFORCEMENT ACTIVITIES IN FOOD SAFETY CONTROL

Inspections and other enforcement activities, ranging from guidance and education to more coercive measures such as administrative procedures, sanctions and prosecutions, are the main form through which the regulated business experiences regulations (Blanc, 2013). The approach adopted by the enforcement agencies, i.e. the way in which the enforcement activities are conducted, influences how the rules are realized (May & Winter, 2011; Blanc, 2013). ‘Enforcement strategy’ refers to the tactical choices made and the different types of actions taken by a regulatory agency, i.e. prioritization regarding the rules to be enforced, items and regulated businesses to be inspected and enforcement methods employed (May & Burby, 1998). The choice of practices and strategies is suggested to be shaped by an agency's underlying approach, or philosophy, to enforcement (May & Burby, 1998). ‘Enforcement style’, in turn, refers to the interaction between an inspector and a regulatee, i.e. whether an inspector is strict or lenient, attempts to enforce the “letter” or the “spirit” of the law, or acts as a consultant explaining the rules or as a policeman enforcing the law (May & Burby, 1998; May, 2004; May & Winter, 2011). The way in which inspectors apply their discretion is influenced by the responsiveness of the regulatee and by the attitudes and assessment of the inspector regarding the ability and willingness of a regulatee to comply (May & Winter, 2011; Lääkkö-Roto et al., 2015).

The motivation of regulatees to comply with regulations is influenced by the enforcement approach by the control official (Ayres & Braithwaite, 1992; May, 2004; Fairman & Yapp, 2005; Yapp & Fairman, 2006; Lääkkö-Roto & Nevas, 2014b). The initial approach of food control officials should be seeking voluntary compliance with legal requirements by the FBOs (Whitehead, 1995). A responsive approach, i.e. adjusting enforcement actions based on the performance and compliance history of the business, starting with an advisory approach and progressing to more formal and coercive actions if co-operation fails to prevent non-compliance, is considered to be optimal in promoting compliance (Ayres & Braithwaite, 1992; Yapp & Fairman, 2006; OECD, 2014). However, other papers have raised questions regarding the applicability of the responsive approach in practical inspection and enforcement encounters (May & Wood, 2003; Mascini & Wijk, 2009). Regulatees may associate responsiveness and flexibility of officials with inconsistent interpretations, which, in turn, may undermine their understanding of rules and weaken compliance (May & Wood, 2003). As regulatees value clarity and consistency in requirements, finding a balance between formal and facilitative approaches and achieving the benefits of co-operation without negative effects of inconsistency poses a challenge for enforcers (May & Wood, 2003).



### **2.6.1 INSPECTIONS AND GUIDANCE**

Several studies have demonstrated the positive influence of inspections on food safety and compliance of FBOs (e.g. Buchholz et al. 2002; Reske et al., 2007; Guiducci et al., 2011; Nevas, et al., 2013; Lääkkö-Roto & Nevas, 2014b; Lääkkö-Roto et al., 2015). However, assessing the direct association between inspection results and food safety indicators is not simple, as restaurant inspection results as such do not necessarily predict the occurrence of foodborne outbreaks (Cruz et al., 2001; Jones et al., 2004; Powell et al., 2013) or correlate with the microbial levels of foodstuffs (Kjeldgaard et al., 2010; Leisner et al. 2014). Moreover, some studies have argued that inspections alone may be insufficient in promoting a major improvement in food premises with recurrent violations (Phillips et al., 2006), and that an increased inspection frequency as such does not straightforwardly improve compliance (Newbold et al., 2008). Officials also tend to focus on evaluating visual or rule-based items rather than critical and risk-based items on inspections, decreasing the value of inspections and raising a need for more training on risk-based approaches for officials (Green & Kane, 2014; Lääkkö-Roto et al., 2015). To increase the risk-basis of food service inspections, use of weighted scores according to severity of the violations is suggested (da Cunha et al., 2016b). Also among high-risk companies producing food of animal origin, an operational inspection scoring tool with promising results has been designed (Stadlmüller et al., 2017).

An advisory approach by enforcement officials has been shown to have an important role in helping small-scale FBOs achieve compliance and improve food safety practices (Fairman & Yapp, 2005; Yapp & Fairman 2006; Buckley, 2015). Among restaurant business operators, a positive association is reported between their attitudes towards official food control and hygiene in their food premises (Lääkkö-Roto & Nevas, 2014b). The attitude towards official control, in turn, is affected by the level of co-operation with the official and by the advisory approach of the official (Lääkkö-Roto & Nevas, 2014b). Also among FBOs of approved establishments, Nevas et al. (2013) emphasize the importance of the guidance given by the inspecting official and the communication between the FBO and official in helping the FBOs to commit to food safety and in raising FBOs' awareness of food safety risks in their operations. The nature of communication and the relationship between the official and the FBO may also influence regulatees' perceptions of consistency of enforcement (Hutter & Amodu, 2009; Mascini & Wijk, 2009; Davies et al., 2014).

### **2.6.2 ENFORCEMENT IN CASE OF NON-COMPLIANCE**

Food control authorities must provide FBOs with the necessary instructions and requests to ensure compliance with food safety regulations (MAF, 2011b). In case an FBO does not comply despite requests, EU food control legislation defines the national enforcement actions to be taken by the competent

authorities (EU, 2004d). The actions may include imposition of sanitation procedures, restriction or prohibition of placing a food on the market, ordering the recall, withdrawal and/or destruction of food, suspension of operations or closure of all or part of the business concerned (EU, 2004d). When deciding which action to take, the authority should take into account the nature of the non-compliance and the compliance history of the FBO (EU, 2004d).

The enforcement actions described in the Finnish Food Act are administrative coercive measures or compulsory procedures (henceforth referred to as “enforcement measures”) (Table 2). The use of enforcement measures comes into question if the FBO has not corrected the observed non-compliances as requested by the food control official and the violations pose a risk of a health hazard (MAF, 2011b). The enforcement process comprises administrative decision-making steps that start from hearing of the FBO regarding the prospective administrative decision, progress to giving the enforcement decision and end with verifying that the FBO complies with the decision and corrects the non-compliances. Administrative enforcement measures differ from the requests given by food control authority or officials with respect to their legal binding force (Evira, 2012a). While requests are not binding on the FBOs and thus do not involve a hearing process or appealable decision, administrative enforcement measures are binding and require the administrative formalities. Neglected requests may, however, be taken into account when considering the use of enforcement measures (Evira, 2012a).

The municipal authority bodies may delegate the competence to apply the enforcement measures referred to in Sections 55–60 of the Finnish Food Act (Table 2) to the holder of the municipal office performing food control tasks such as the head of the unit or inspecting officials (MAF, 2011b). In urgent cases of severe health hazard, all municipal food control officials have the right to apply enforcement measures referred to in Sections 55, 56 and 58 of the Finnish Food Act even if no authority is delegated within the unit. Such decisions shall be submitted to the municipal authority body for consideration without delay (MAF, 2011b).

**Table 2.** Administrative enforcement measures available for local food control authorities based on the Finnish Food Act (MAF, 2011b).

Administrative enforcement measure (section)	Definition and purpose of use
Order to remove violations of food regulations (55 §)	The FBO may be ordered to remove violations if foodstuff, food premises, operations or information given on food may cause a health hazard or mislead the consumer, or otherwise violate the food regulations. The violations shall be ordered to be removed immediately or within a time limit.
Prohibition (56 §)	The manufacture, placing on the market or serving of a foodstuff may be prohibited if the food or information about it, food premises, or the operations may cause a reasonable risk of a serious health hazard that cannot otherwise be prevented.
Ordering a withdrawal of food from the market and informing public (57 §)	The FBO may be ordered to withdraw a foodstuff from the market and inform the public of the foodstuff if the foodstuff or information given on it violates food safety requirements and the FBO fails to comply with the obligation laid down in Article 19 of the General Food Regulation (EC No 178/2002).
Seizure (58 §)	If other measures are not sufficient, a foodstuff that causes or reasonably may cause a direct health hazard may be seized in the presence of a witness and kept appropriately marked in food premises or in a sealed or otherwise marked storage space.
Decision on the use or disposal of a foodstuff (59 §)	A foodstuff that is in violation of the food regulations and cannot be used for original purposes may be decided to be used for another purpose. If the use of food is not possible or the food regulations so require, the food must be ordered to be destroyed.
Rejecting foodstuffs of animal origin supplied from another Member State of the European Union at the first destination (60 §)	A foodstuff of animal origin supplied from another EU member state at the first destination shall be rejected if it does not comply with the requirements defined in Section 60 of the Finnish Food Act (Food Act, 2011) concerning salmonella testing <sup>a</sup> , other microbial and chemical qualities, temperature or traceability of foodstuff.

**Table 2.** (Continued)

Administrative enforcement measure (section)	Definition and purpose of use
Cancelling the approval of food premises (61 §)	If there is no other way of preventing a health hazard, approval of food premises may be cancelled. Approval may also be cancelled if the premises or the operations violate the food regulations critically and the FBO has not complied with an order or prohibition given. Approval may be cancelled in full or in part and until further notice or for a fixed period of time.
Urgent measures (63 §)	In urgent cases, an official performing municipal food control tasks has the right to apply an order, prohibition or seizure even if no power has been delegated from the municipal food control authority body. Urgent measures applied by an official shall be immediately submitted to the municipal food control authority for consideration.
Penalty payments, threat of performance and threat of suspension (68 §)	An order or prohibition issued with a penalty payment, a threat of performance at the FBO's expense or a threat of suspension.

<sup>a</sup> Finland has the right to demand specific salmonella certificate and testing for imported meat, minced meat and eggs due to granted additional salmonella guarantees (EU, 2004b).

### **2.6.2.1 Good governance in food control decision-making**

The food control authorities use public power when applying enforcement measures, which may restrict the constitutional freedom of an FBO to engage in commercial activity or the right of protection of property (Lepistö, 2008; Lepistö & Hänninen, 2011). The authorities shall thus follow the legal requirements for administration and the principles of good governance laid down in Administrative Procedure Act 434/2003 (Ministry of Justice, 2003) and Constitution of Finland 731/1999 (Ministry of Justice, 2011). The governance shall be open and equal to everyone. Everyone should have her/his matter dealt with appropriately and without undue delay and receive a reasoned decision with the right of appeal (Ministry of Justice, 2003, 2011). The actions of an authority should be objective and relative to their aims (Ministry of Justice, 2003).

Before a matter is decided, the authority should carry out a hearing procedure, in which the party concerned is given an opportunity to express her/his opinion and an explanation on the matter and to submit information which may have an effect on the decision (Ministry of Justice, 2003). The hearing should be in written form, unless an oral hearing is requested by the party (Ministry of Justice, 2003). The enforcement decision shall be provided in writing, indicating the action to be taken, the time limit for the action and the reasons for the decision, and information on the rights of the FBO to appeal the decision (EU, 2004d; Ministry of Justice, 2003). In case of an urgent matter, the decision may be issued orally, but without delay, it shall be issued in written form and provided with instructions for an appeal (Ministry of Justice, 2003).

### **2.6.2.2 Use of administrative enforcement measures in Finland**

Studies on the use of enforcement measures in Finnish environmental health and food control have mainly focused on the realization of the principles of good governance and the effects of the legal aspects in their use (Lepistö, 2008; Lepistö et al., 2009; Lepistö & Hänninen, 2011) and the perceptions of the food control officials regarding the use of the measures (Jokela et al., 2009). In addition, Pahkala (2012) has investigated the use of enforcement measures in the largest control unit in Finland, the City of Helsinki Environment Centre. The studies have reported that the use of enforcement measures in Finnish food control is relatively infrequent, possibly due to uncertainty of food control officials concerning the enforcement practices (Lepistö, 2008; Jokela et al., 2009; Lepistö et al., 2009, Lepistö & Hänninen, 2011). Although enforcement measures are mainly seen as important in strengthening food control actions and improving food safety (Jokela et al., 2009; Lepistö & Hänninen, 2011), the administrative procedures are often

perceived as laborious, demanding, time-consuming and rather ineffective (Lepistö, 2008; Lepistö & Hänninen, 2011).

Enforcement measures appear to be a necessary control measure for eliminating health hazards in food business operations, as the measures are especially used when an FBO has multiple or severe non-compliances recorded as contributing or risk factors for foodborne illnesses (Lundén, 2013). However, Lepistö (2008) noted that poor knowledge and uncertainty in municipal control units have limited the use of enforcement measures and even resulted in disuse or passive authority. According to the audits of local food control conducted by Regional State Administrative Agencies, the use of enforcement measures has been insufficient (Evira, 2014b).

Noticeable differences and shortcomings among the local food control units have been reported in administrative practices, protecting legal rights and realization of the principles of good governance (Lepistö, 2008). Major deficiencies were observed in the hearing process, presenting legal arguments for decisions and providing directions for appeals (Lepistö, 2008). Also among official veterinarians in slaughterhouses, the veterinarians in slaughterhouses showing severe non-compliances seem to have less expertise in administrative procedures than their peers in other slaughterhouses (Luukkanen & Lundén, 2016). As concluded by Lepistö (2008), good governance affects the elimination of health hazards and the efficacy of enforcement measures and control in general. Deficiencies in the administrative formalities, such as the hearing process or legal argumentation of the decisions, are likely reasons for repeal of the decision in the appellate courts, which may endanger or prolong the removal of health hazards (Lepistö, 2008).

To develop the administrative procedure and expertise of officials, uniform guidelines, support and encouragement from the central authority, templates and judicial aid are required (Lepistö & Hänninen, 2011; Luukkanen & Lundén, 2016). The positive impacts of increased guidance on the use of enforcement measures have been noted in EU member states (COM, 2013). In Finland, Evira has provided a national guideline for using enforcement measures (Evira, 2012a) as well as templates for the enforcement decisions available for food control officials. Despite these improvements and enhanced guidance, a recent report of private pilot audits of environmental health and food control units indicates that the culture of control varies between the units from an advisory and negotiative approach to firm and rapid authoritative activity, and differences in the use of enforcement measures and certain shortcomings in the practices were still observed (Lepistö, 2016).

The findings of previous studies have indicated a need for further research on the use of enforcement measures and related challenges. Particularly, the efficacy of enforcement procedures in inducing compliance and the durations of the procedures remain unknown. Moreover, the factors affecting whether enforcement measures are used or not warrant investigation.

## **2.6.3 DISCLOSURE OF FOOD CONTROL INFORMATION**

### **2.6.3.1 *Benefits and challenges of publishing control information***

Publishing the inspection reports of food premises aims at increasing the efficacy of enforcement by enhancing the incentives of FBOs to comply (Ho, 2012; Djekic et al., 2014; Evira, 2015b; da Cunha et al., 2016a). Disclosing the inspection reports at the food premises and/or on the internet showing grades or scores is the choice of several countries and large cities, e.g. Denmark (Danish Veterinary and Food Administration [DVFA], 2015), UK (Worsfold & Worsfold, 2008; Food Standards Agency of United Kingdom [FSA UK], 2017a), Toronto (Thompson et al., 2005) and New York (New York City, 2017). Among food services, the public posting of inspection results has been reported to promote food safety and compliance (Jin & Leslie 2003; Simon et al., 2005; Thompson et al., 2005; Serapiglia et al., 2007; Wong et al., 2015).

Disclosure of inspection results is considered to enhance transparency of official control and food business and to be an effective means of communicating food safety risks to consumers (Filion & Powell, 2009; Ho, 2012; Papadopoulos et al., 2012; Evira, 2013, 2015b; Djekic et al., 2014; da Cunha et al., 2016a). For instance, in Denmark, consumers are very familiar with the grading scheme, “Smiley” (DVFA, 2015). However, studies in other countries have reported less awareness and influence of the grading systems among consumers (Shahid & Whisson, 2012). Moreover, although one core aim of the disclosure systems is to harmonize the inspection practices (Thompson et al., 2005; Evira, 2013, 2015b), variation in grading between authorities is a challenge (Worsfold & Worsfold, 2007; Ho, 2012).

Some countries also publish other enforcement information alongside inspection results. For instance, the Food Safety Authority of Ireland (FSAI) maintains a public online database for enforcement order reports and successful prosecutions (FSAI, 2017). The database is updated every working day and includes closure, improvement and prohibition orders issued to FBOs, and the reports remain in the website for a period of one to three months from the date the order was lifted (FSAI, 2017). Also the FSA UK publishes an online register for successful food law prosecution outcomes acquired by the FSA UK and local food authorities in England, Wales and Northern Ireland (FSA UK, 2017b).

### **2.6.3.2 *Finnish Oiva evaluation system***

Based on the obligation of FBOs and control authorities to disclose the document on the inspection of the food premises set in the Finnish Food Act (MAF, 2011b), a national system for publishing the inspection reports (Oiva evaluation system) has been adopted since 2013 in the retail sector and since 2015 in all food business industries in Finland (Evira, 2013). The Oiva

inspections are conducted based on standardized evaluation criteria covering widely food hygiene, information given about foods and traceability of food items. The criteria are separate for registered food premises, such as restaurants, retail stores or bakeries, and for approved food premises, including dairy, fishery and meat establishments. The structure and layout of the Oiva report are standardized across the country (Evira, 2013). According to the order given by Evira, retail FBOs are obliged to publish the Oiva inspection report at the entrance of the food premises or in other place easily accessible to customers, and all food companies must publish the report on their web page if they market foodstuff via webpages (Evira, 2016b). The evaluation criteria, inspection guidelines and Oiva inspection reports are publically available for FBOs and consumers and published online (Evira, 2017e).

For each inspected item, based on the severity and recurrence of the observed food safety violation, the evaluation criteria define the Oiva grade to be given and determine the control actions that the food control officials should take (Evira, 2013). Smiley grades, ranging from A (“excellent”), B (“good”), C (“to be corrected”) to D (“poor”), are used to indicate the inspection result for each inspected item, and the lowest grade of all inspected areas determines the overall grade for the inspection (Evira, 2013). Since introduction of the Oiva system, the vast majority of all inspected FBOs have been given a grade A or B, in 2016 the combined share of the best grades (A + B) being 86% (Evira, 2017e).

One aim of the Oiva system is to improve the efficacy and risk-basis of inspections (Evira, 2015b). According to the evaluation guidelines, food control authorities should always initiate an administrative enforcement process if the FBO is given a grade D, indicating that food safety is jeopardized or the consumer is being considerably misled (Evira, 2016d). Also if the non-compliance impairs food safety or misleads the consumer (grade C) and if other control measures are inadequate, or if the non-compliance is recurrent, administrative enforcement measures should be used (Evira, 2016d).

Thus far, only a few studies have investigated the Oiva evaluation system. Hallberg (2016) reports that the Oiva system is not very well known among consumers, and thus, the system has little influence on consumer’s choice of retail store. Juppi (2015) concludes that although the food control officials and retail FBOs consider that the Oiva system standardizes inspections and enhances correction of violations, further harmonization of the practices, improved clarity of evaluation guidelines and consumer familiarity with the system are needed.

No scientific literature about the applicability of the disclosure systems from the viewpoint of FBOs in approved establishments before retail stage exists. Furthermore, previous studies in Finland discussing the opinions of FBOs regarding the official food control (Tähkääpää et al., 2009a; Nevas et al., 2013, Lääkkö-Roto & Nevas, 2014b; Lääkkö-Roto et al., 2015) were conducted before introducing the Oiva system. It is thus unknown whether the changes



in the control system in the form of harmonized guidelines and publication of inspection results have influenced the views of FBOs on the importance and consistency of official food control overall. In addition, the influence of the Oiva evaluation system on the use of administrative enforcement measures has not been investigated.

### 3 AIMS OF THE STUDY

The principal objective of this study was to investigate the risk-basis, efficacy and consistency of enforcement of food safety legislation at the local level in Finland. The topic was examined by exploring the views and control actions of food control officials and by surveying the perceptions of FBOs. The study aims at discovering ways to improve the risk-basis, efficacy and consistency of enforcement practices.

Specific aims of the study were as follows:

1. To analyse the risk-basis of enforcement by examining how the types of food safety violations and the control history of FBOs affect the use of administrative enforcement measures in local food control units (I, III)
2. To evaluate the efficacy of using administrative enforcement measures in the units by investigating the correction of violations and durations of enforcement processes (I).
3. To explore factors affecting and challenging the use of administrative enforcement measures in local food control units (II, III).
4. To investigate the perceptions of Finnish FBOs of approved dairy, fishery and meat establishments under municipal food control regarding the importance of official control for the food safety of their company and how they experience the consistency of official food control (IV).
5. To assess preliminary effects of the Oiva evaluation system on the use of administrative enforcement measures (III) and to explore how the FBOs in approved establishments perceive the system in its early stages (IV).

## **4 MATERIALS AND METHODS**

The material of the study consisted of analysis of administrative enforcement decisions and related documents by local food control authorities (I), survey (II, III) and interviews (III) of local food control officials on the use of administrative enforcement measures and related challenges, analysis of inspection reports of retail and food-serving FBOs (III) and surveys to FBOs in approved dairy, fishery and meat establishments under municipal food control (IV). Both quantitative and qualitative data analysis methods were used.

### **4.1 ADMINISTRATIVE ENFORCEMENT DECISIONS (I)**

Administrative enforcement decisions and related documents from January 2008 to September 2011 were requested from 29 selected units, representing 34% of the units at that time, in September 2011. The sample included the largest units, based on the number of inhabitants, and randomly chosen smaller units to cover all regions of the six Regional State Administrative Agencies. Enforcement cases (n = 188) from 19 units were analysed; 10 of the sample units had not used enforcement measures during the study period. Data concerning the labour resources of the units and the number of food premises in the area of the units were collected from an Evira report (Evira, 2011).

Each enforcement case, including one to several violations, was analysed to determine the type of violations within the cases, whether compliance was achieved, persistence of violations before initiation of the enforcement process in days (pre-enforcement process), duration of the enforcement process in days, which enforcement measures had been used and whether enforcement measures were recurrently used due to repeated violations. The duration of the pre-enforcement process was counted from the date the authority detected the violation to the date the FBO was heard of a prospective enforcement decision, and the enforcement process from the date of hearing to the date compliance was verified.

## **4.2 ELECTRONIC QUESTIONNAIRE FOR FOOD CONTROL OFFICIALS AND HEADS OF THE UNITS (II, III)**

An electronic questionnaire (E-lomake, Eduix Oy) was developed and sent to all units (n = 62), excluding the autonomous region of Åland, in September 2015 (II, III). The head of the unit and officials conducting food inspections (henceforth “inspectors”) received partly tailored versions of the questionnaire. The questionnaire was mainly structured, consisting of a four-point Likert scale and other closed questions about whether enforcement measures had been used in their unit within the last three years and the opinions of respondents about enforcement measures, adequacy of available training, quality of national guidance, consistency in the use of enforcement measures and the expertise of both themselves and the head of their unit (II). Respondents were also asked about delegation of authority regarding the use of enforcement measures and whether their unit has an internal guideline and templates for enforcement decisions (II). In addition, the respondents were asked about their opinions of the influence of the Oiva evaluation system on the use of enforcement measures (III). The respondents could also elaborate on their answers in two specified open-ended questions: 1) “Is there something you perceive as problematic, difficult or laborious in the use of enforcement measures?” and 2) “You may freely express your opinions about enforcement measures.” (II) and in general open-ended questions (“Other, please specify”) subsequent to closed questions regarding the Oiva system (III). If not indicated in the survey, the data concerning the labour resources of the units and the number of food premises in the areas of units were collected from the internet pages of the units (II).

## **4.3 OIVA INSPECTION REPORTS (III)**

Within the control areas of the 45 units that participated in the electronic survey (II, III), the national food control database was searched to find the food serving and/or preparing premises and retail stores for which there was no record on using enforcement measures despite a given grade D in 2014. The sample included a total of 75 food premises located within the areas of 15 units. For these food premises, the Oiva inspection reports (n = 305) from May 2013 until December 2015 were collected from the database.

## **4.4 INTERVIEWS OF FOOD CONTROL OFFICIALS (III)**

To uncover factors related to control history of the FBO and alignments in the units that may have influenced using or not using enforcement measures in

the cases of the 75 FBOs given a grade D in 2014, a semi-structured interview form was developed. Between December 2015 and March 2016, telephone interviews were conducted with the officials who had inspected these FBOs. A total of 42 officials, ranging from 1 to 7 per unit, were interviewed. Of these, 18 had inspected more than one of the sample food premises. In five cases, the official who had conducted the control actions was not available for interview and a colleague or superior was interviewed instead.

During the interviews the officials were asked whether enforcement measures had been used in the cases, and if not, why. The interviewees were also inquired about alignments in their unit regarding the use of enforcement measures if a grade D is given to a FBO. The questions comprised multiple choice and open questions. The officials were grouped according to their units.

#### **4.5 QUESTIONNAIRE FOR FBOS (IV)**

A structured questionnaire was developed on the basis of a form used in restaurant business operator interviews by Lääkkö-Roto and Nevas (2014b) and sent to all approved meat, fishery and dairy product establishments under municipal food control in Finland, excluding the establishments located in the autonomous region of Åland. The survey was carried out between October 2015 and February 2016. The list of the establishments was acquired from the public register of Evira (Evira, 2015a), and the number of establishments receiving the questionnaire was 630. The inquiry was sent as an electronic questionnaire (E-lomake, Eduix Oy) (n = 333) or as a printed version (n = 297), depending on the public availability of e-mail addresses of the companies. The e-mail addresses of the FBOs of approved establishments were obtained from the internet, or if no e-mail addresses were found, the postal addresses of the companies were acquired from the Evira register (Evira, 2015a).

The questionnaire inquired about the opinions of FBOs regarding the importance and consistency of official food control, relevance and efficacy of official control actions, optimal inspection frequency and quality of inspections. In addition, the perceptions of FBOs regarding the interaction with the official and their views of the Oiva evaluation system were of interest. The majority of the questions were closed questions for which respondents were asked to choose from a fixed number of given options or state their opinion to given claims in a five-point Likert scale. In evaluating the hygiene status of their establishment and the quality of official food control, FBOs used Finnish school grades (4 = fail, 5 = poor, 6 = fair, 7 = satisfactory, 8 = good, 9 = very good, 10 = excellent). Three open-ended questions allowed the respondents to state their opinions of the topics of the survey and to elaborate on their answers: 1) “What does uniformity of official control mean in your opinion?”, 2) “What kind of thoughts, hopes or fears does the Oiva evaluation

system evoke in you?” and 3) “You may freely express your opinions about uniformity and efficacy of official food control”.

## **4.6 STATISTICAL ANALYSIS**

Statistical analysis of the data was carried out using SPSS Statistics (IBM SPSS Statistics, NY, USA) v. 20.0 (I) or v. 22.0 (II-IV). Non-parametric tests were applied as the variables included in the analyses appeared not to be normally distributed according to the Kolmogorov-Smirnov test, many variables were discrete and the sample sizes were rather small in some analyses. In the statistical analyses of the survey responses (II-IV), the “I don’t know” answers were categorized as missing. In counting the durations of enforcement processes (I), deficient information of outcome was defined as missing. Cronbach’s alpha was used to examine the reliability of the created sum variables in Study IV. Statistical significance was accepted at two-tailed p-values < 0.05.

### **4.6.1 STATISTICAL ANALYSIS OF DATA ON ADMINISTRATIVE ENFORCEMENT DECISIONS (I)**

Violations (n = 541) were categorized as critical (n = 236) or non-critical (n = 305) based on studies on the likelihood of food safety violations directly contributing to food contamination or foodborne outbreaks (Jones et al., 2004; Reske et al., 2007; Evira, 2012b; US FDA, 2013). Critically defined violations comprised six categories: traceability, temperature control, cleanliness of equipment or surface in contact with food, operational or personal hygiene, hand-washing and personal hygiene facilities, and food quality and safety. The durations of pre-enforcement and enforcement processes were analysed according to each violation within a case. Differences between critical and non-critical violations in pre-enforcement and enforcement process durations were analysed by using a Mann-Whitney U test. Spearman’s rho was used to analyse the correlations between the number of enforcement cases and the labour resources of the unit and the number of food premises in the areas of the units.

### **4.6.2 STATISTICAL ANALYSIS OF DATA ON QUESTIONNAIRE FOR FOOD CONTROL OFFICIALS (II, III)**

The respondents were grouped into the heads of the unit and inspectors, and the inspectors were further stratified based on whether they had initiated enforcement processes themselves within the last three years or not (henceforth “enforcer inspectors” and “non-enforcer inspectors”). Categorization at the unit level was made based on the use of enforcement

measures within the last three years (henceforth “enforcer units” and “non-enforcer units”) and number of labour resources of the unit (small unit = resources equal to or less than the median of the responding units; large unit = resources greater than said median).

To compare the units based on their prerequisites for using enforcement measures, the units were scored on six factors: 1) existence of an internal guideline for the use of enforcement measures, 2) availability of templates for enforcement decisions, 3) availability of templates for urgent enforcement measures, 4) whether enforcement measures are discussed in meetings or otherwise in the unit, 5) participation of at least one of the respondents of the unit in training related to the use of enforcement measures and 6) delegation of authority to use enforcement measures from the municipal organ to the head of the unit and/or to the inspectors. One point was gained for each factor existing in the unit, and the mean of the total points of the unit formed the final scores for each unit. Units without valid information for at least half of the factors were excluded from scoring. A two-tailed Mann-Whitney U test was conducted to analyse the differences between enforcer and non-enforcer units and between large and small units in scoring, labour resources and number of food premises. Kruskal-Wallis test was used to analyse regional differences among the units in the scoring. Comparison of groups with nominal variables was conducted by using Fisher’s exact test.

#### **4.6.3 STATISTICAL ANALYSIS OF DATA ON OIVA INSPECTION REPORTS (III)**

Based on Oiva evaluation guidelines for notified food premises (Evira, 2016d), the D-graded non-compliances recorded in the inspection reports were categorized into 17 main categories. Fisher’s exact test was used to compare the compliance history of the FBOs between cases based on whether or not an enforcement process was initiated.

#### **4.6.4 STATISTICAL ANALYSIS OF DATA ON QUESTIONNAIRE FOR FBOs (IV)**

The responding establishments were categorized based on main type of production and their regional location. For comparison of the establishments based on size, the establishments were categorized into micro- (< 10 employees), small- (10 - 49 employees), medium- (50 - 249 employees) and large-sized ( $\geq$  250 employees) enterprises. Two sum variables were created to compare the FBOs’ opinions of 1) the hygiene status of their establishment and 2) the quality of official food control. The first sum variable (n of variables = 5, Cronbach’s alpha = 0.874) consisted of the grades given by FBOs to 1) operational hygiene, 2) compliance with legislation, 3) safety of the foods manufactured, 4) willingness to correct food safety violations and 5) overall food hygiene of their establishment. The second sum variable (n of variables =

6, Cronbach's alpha = 0.959) consisted of the grades given by FBOs to 1) inspections, 2) guidance given by the official, 3) willingness of the official to negotiate, 4) inspection reports, 5) attitude of the official towards the establishment and 6) overall control of the establishment. Pearson Chi-square exact test was used to analyse the differences between establishments grouped by size, and the correlations between discrete and continuous variables were evaluated by using Spearman's rho. Kruskal-Wallis test was applied to analyse the differences in the sum variables between establishments grouped by size and main type of production.

#### **4.7 QUALITATIVE ANALYSIS (II-IV)**

The qualitative data acquired from the responses to the open-ended questions in the surveys for food control officials (II, III) and FBOS (IV) were analysed by using content analysis, in which the data are systematically coded and categorized to identify themes and patterns (O'Cathain & Thomas, 2004; Hsieh & Shannon, 2005; Elo & Kyngäs, 2008; Vaismoradi et al., 2013). The steps of the analysis, including familiarization with the data, initial coding of the answers, devising the coding frame and generation of the themes, were manually conducted, utilizing Microsoft Excel 2013 software (Microsoft Corporation, 2012).



## **5 RESULTS**

### **5.1 BACKGROUND INFORMATION ON USE OF ENFORCEMENT MEASURES AND SURVEY RESPONDENTS (I-IV)**

#### **5.1.1 ENFORCEMENT CASES IN 2008–2011 (I)**

During 2008-2011, 66% (19/29) of the units involved in the study had used enforcement measures. In the units that used enforcement measures, the number of enforcement cases ranged from 1–113 cases per unit and 0.10–2.34 cases per 100 food premises. No correlation was observed between the number of enforcement cases per unit and the number of food premises or the labour resources of the unit (Spearman's rho  $p > 0.05$ ).

#### **5.1.2 QUESTIONNAIRE FOR FOOD CONTROL OFFICIALS (II, III)**

A total of 129 responses from 73% (45/62) of the units, from the regions of all six Regional State Administrative Agencies, were received. Of the respondents, 28 (22%) were the heads of the unit and 101 (78 %) were inspectors (Table 3). In 87% (39/45) of the units, enforcement measures had been used in the last three years. The labour resources for performing official food control tasks in the responding units were higher in enforcer units than in non-enforcer units (Mann-Whitney U test,  $p = 0.031$ ) (Table 3). Also the number of food premises in the area of the unit was higher in enforcer units than in non-enforcer units (Table 3), but the difference was not significant (Mann-Whitney U test,  $p = 0.092$ ). Of the inspectors, 61% (62/101) had used enforcement measures themselves.

**Table 3.** *Background information of the units (n = 45) categorized according to whether enforcement measures had been used in the units during the last three years (II). One inspector did not indicate the applicable unit, and thus, it could not be categorized as an enforcer or non-enforcer unit.*

Factor related to the unit	Enforcer unit (n = 39)	Non-enforcer unit (n = 6)	Total
Number of respondents	120	8	128
Inspectors	93	7	100
Heads	27	1	28
Median of labour resources <sup>a</sup> for performing food control tasks [range]	4.0 [1.7 - 33.0]	3.0 [1.0 - 4.0]	4.0 [1.0 - 33.0]
Median of number of food premises in the unit's area <sup>b</sup> [range]	845 [180 - 5320]	328 [313 - 379]	717 [180 - 5320]
Size of the unit categorized according to labour resources <sup>c</sup>			
Small	17	5	22
Large	16	0	16

<sup>a</sup> Data on labour resources were available for 38 units.

<sup>b</sup> Data on number of food premises in the unit's area were available for 37 units.

<sup>c</sup> Small unit = labour resources equal to or less than the median ( $\leq 4$  person-years); large unit = labour resources greater than the median ( $> 4$  person-years).

### 5.1.3 D-GRADED CASES IN 2014 (III)

Even though not reported in the national food control database, an enforcement process was actually initiated in 39% (29/75) of the D-graded cases as revealed by analysis of inspection reports and interviews of officials. In 61% (46/75) of the cases, no enforcement process was initiated. D-graded violations were observed in a total of 12 main categories of the inspected items.

### 5.1.4 QUESTIONNAIRE FOR FBOS (IV)

The survey yielded a total of 136 responses (response rate 22%), covering the areas of 79% of units and the regions of all six Regional State Administrative Agencies. The majority of the establishments of the responding FBOs were micro-sized, employing less than ten persons (Table 4). The proportions of the responding establishments, based on the main type of production and the regional distribution, corresponded well with the distribution of all establishments in Finland, based on the Evira register (Evira, 2015a). An Oiva inspection had been conducted in 73% (87/119) of the establishments. Based on the sum variable created for the hygiene status of their establishment, the mean grade of all establishments was 8.9 (range 7.0-10.0), and the mean grades given by dairy, fishery and meat establishments were 9.2, 8.8 and 9.0,

respectively (Kruskal-Wallis test,  $p = 0.007$ ). Among establishments grouped by size, no significant differences were observed in the mean grades of the sum variable created for the hygiene status.

**Table 4.** *Responding FBOs according to main type of production and size of establishment (IV).*

Factor related to FBO	Main type of production % of responding FBOs (n/N)			Total
	Dairy	Fishery	Meat	
All FBOs	18 (24/136)	47 (64/136)	35 (48/136)	100 (136/136)
Size of establishment <sup>a</sup>				
Micro (< 10 employees)	50 (12/24)	77 (46/60)	56 (27/48)	64 (85/132)
Small (10 - 49 employees)	8 (2/24)	15 (9/60)	19 (9/48)	15 (20/132)
Medium (50 - 249 employees)	25 (6/24)	8 (5/60)	21 (10/48)	16 (21/132)
Large ( $\geq$ 250 employees)	17 (4/24)	0 (0/60)	4 (2/48)	5 (6/132)

<sup>a</sup> Four FBOs did not indicate the number of employees in their establishment.

## 5.2 RISK-BASIS OF ENFORCEMENT (I, III, IV)

### 5.2.1 RISK-BASIS IN INITIATION OF AN ENFORCEMENT PROCESS (I, III)

Of the enforcement cases during 2008-2011, 64% (120/188) had more than one violation and 79% (149/188) had critical violations (I). The most common violations mentioned in the enforcement decisions were related to infrastructure of the premises (42% of cases), traceability of foodstuff (36%), self-checking system (27%) or other non-compliance (36%) such as improper or misleading labelling.

The most common enforcement measures used were an order (77%; 414/541 of all violations) and a prohibition (41%; 222/541) (I). A prohibition was particularly often used in critical violations (56%; 132/236 of critical violations). In 8% (42/541) of all violations, a given order or prohibition was reinforced by imposing a threat of a penalty payment or suspension of operations.

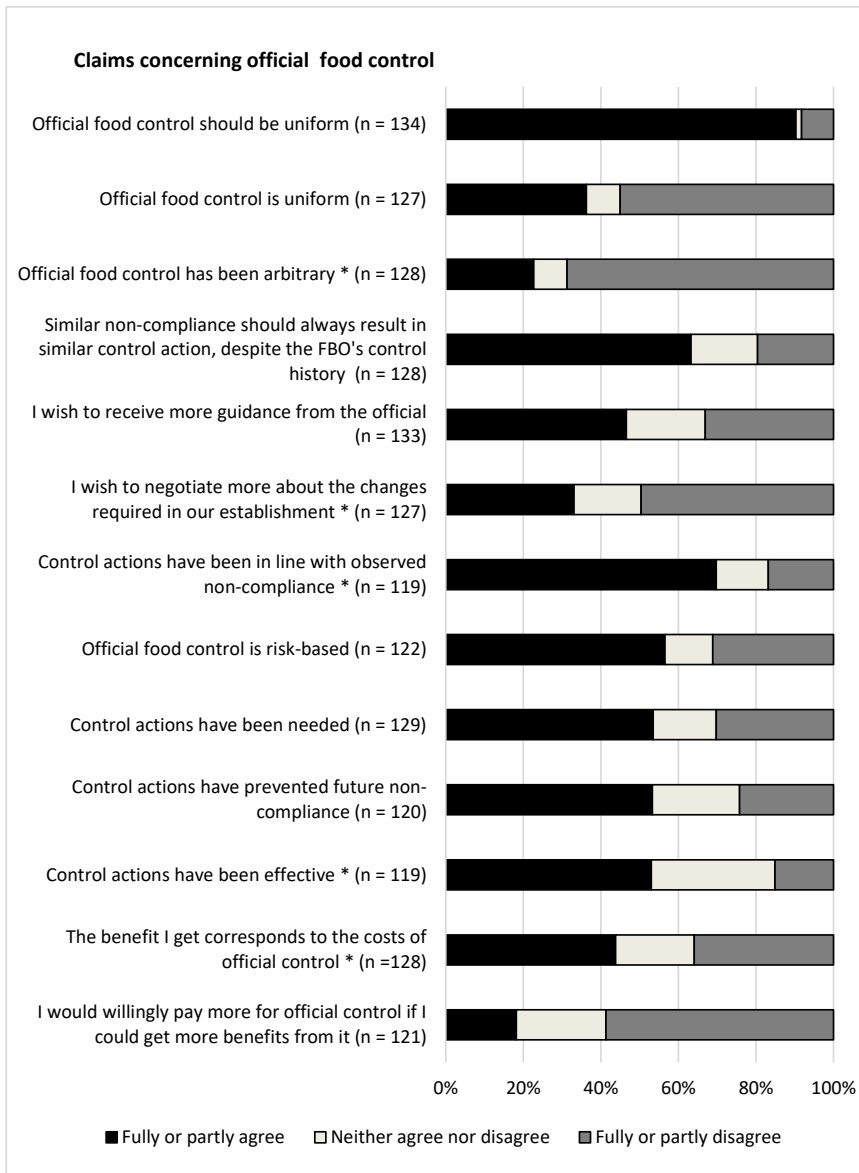
Analysis of the inspection reports of D-graded cases in 2014 indicated that 37% (28/75) of the FBOs were given a grade D for more than one inspected items (III). The most commonly reported violations were related to temperature control and prevention of cross-contamination during

preparation and storage (37% of cases), temperature control and prevention of cross-contamination during serving and selling (29%) and self-checking plan (29%). Based on the analysis of the compliance history of the FBOs, 37% (28/75) had been given a prior grade C in 2014 for the same inspected items that were eventually given a grade D. Among the cases in which an enforcement process was initiated, the FBO had more than one D-graded violation in 59% (17/29) of cases and had been given a prior grade C for the same inspected items in 66% (19/29) of cases, while the corresponding proportions among cases in which an enforcement process was not initiated were 24% (11/46) and 20% (9/46) (Fisher's exact test,  $p = 0.003$  and  $p < 0.001$ ). Of the FBOs inspected based on the Oiva system in the previous year of 2013 ( $n = 23$ ), 91% (21/23) had already then been given a grade C or D for the same or another inspected item that was graded D in 2014.

The risk-based assessment was highlighted in the responses of the interviewed officials regarding the reasons for not using enforcement measures despite an assigned grade D (III). According to the officials, the non-compliance was corrected during a set time limit in more than half of the cases (52%; 24/46) or already during the inspection visit (30%; 14/46). In 13% (6/46) of cases, the given reason was that the non-compliance did not jeopardize food safety, although graded as D. In almost one-third of the cases, more than one reason was given for not using enforcement measures.

## **5.2.2 NECESSITY AND RISK-BASIS OF OFFICIAL FOOD CONTROL IN THE OPINION OF FBOS (IV)**

Official food control was considered to be important for the food safety of their establishment in the opinion of 85% (112/132) of the responding FBOs and for their economic success in the opinion of 74% (96/129). A majority (82%; 110/134) of the FBOs also considered that the official "always" or "most often" focuses on relevant subjects during the inspections. Of the small-sized FBOs, however, significantly lower numbers (50%; 10/20) were of this opinion (Pearson Chi-square exact test,  $p = 0.001$ ). When requested their opinion of an optimal inspection frequency of their establishment, 53% (70/132) of all FBOs but 70% (14/20) of the small FBOs stated that it should be less frequent than the current one determined by the official. Moreover, only half of the FBOs agreed that official food control is risk-based or that the control actions were needed (Figure 1). Small-sized FBOs were particularly critical of the control actions being in line with the observed non-compliance, as only 47% (8/17) of them agreed with the claim.



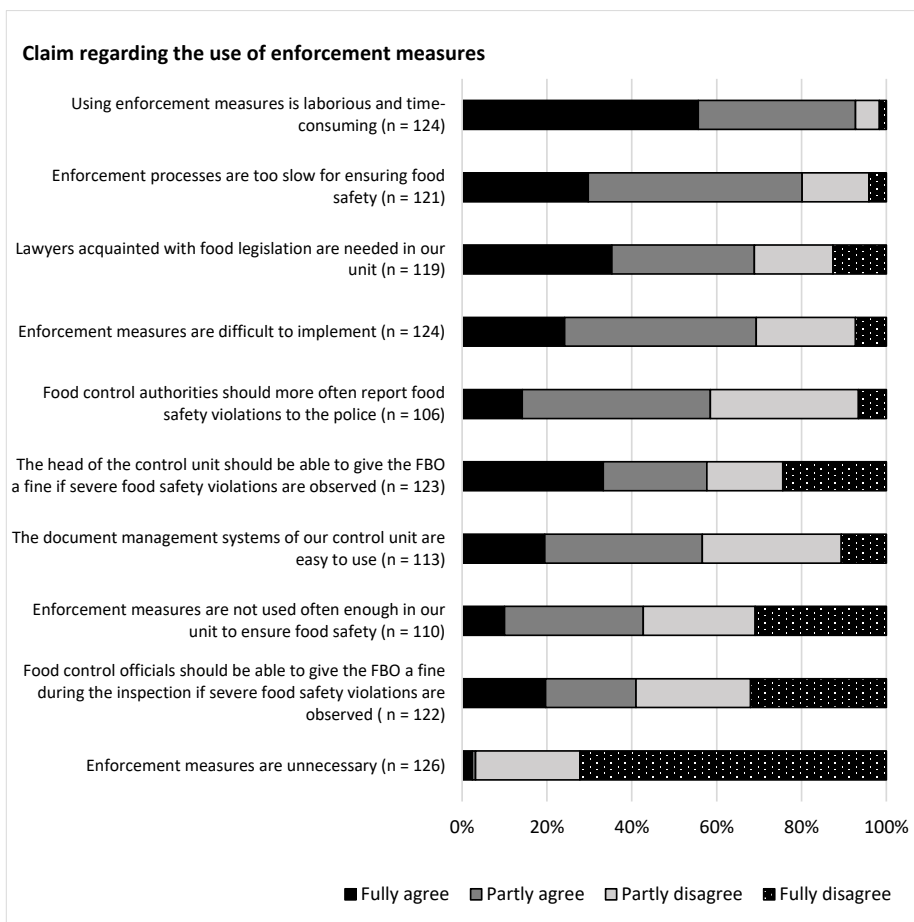
**Figure 1.** Opinions of FBOs about official food control and its necessity, uniformity and efficacy (IV).  
 \* An asterisk indicates a significant difference in the share of the responses among FBOs grouped according to the size of the establishment (Pearson Chi-square exact test,  $p < 0.005$ ).

## **5.3 EFFICACY OF ENFORCEMENT (I-IV)**

### **5.3.1 CORRECTION OF NON-COMPLIANCES (I-III)**

Based on the survey to food control officials (II), almost all officials perceived enforcement measures as necessary for food control (Figure 2), and 84% (35/42) of the enforcer inspectors “fully” or “partly” agreed that the use of enforcement measures had improved food safety in the food premises in which enforcement measures had been used. However, 43% (47/110) of the officials noted that enforcement measures may not be used in their unit often enough, and up to 58% (61/106) considered that food safety violations should be more often reported to the police (Figure 2). Of the respondents, 80% (97/121) stated that the enforcement procedure is too slow to ensure food safety and 58% (71/123) agreed that the head of the unit should have the right to fine a FBO in case of severe food safety violations (Figure 2). However, only 41% (50/122) of the respondents agreed that the officials should have a right to impose an on-site fine during the inspection (Figure 2).

Among the enforcement cases during 2008-2011 (I), the use of enforcement measures led to compliance or cessation of non-compliant operations in 87% (472/541) of the violations. In the rest of the violations, case resolution remained unclear or compliance was not achieved. All violations in which the given enforcement decision had been reinforced by imposing a threat of a penalty payment or suspension of operations resulted in compliance.



**Figure 2.** Opinions of food control officials (n = 129) on the use of enforcement measures in their unit, the enforcement procedure and the need for stricter control measures to intervene in food safety violations (II).

Before using enforcement measures, the authority had issued the FBO a request to correct the detected violations more often in non-critical than in critical violations (Table 5) (I). The median duration of pre-enforcement processes was 14 days and that of enforcement processes 57 days, both being significantly shorter in critical violations than in non-critical violations (Table 5). In 9% (43/469) of the violations, the enforcement process took more than one year. The median duration of enforcement process for violations in which the given decision was reinforced with a penalty payment or a threat of suspension was substantially longer (116 days) than the median of all violations (57 days).

**Table 5.** Durations of the pre-enforcement and enforcement processes and the proportion of violations with a preceding request to correct them before initiating an enforcement process in critical and non-critical violations (I).

Factor related to the process	All violations	Critical violations <sup>a</sup>	Non-critical violations
Median duration of pre-enforcement process in days [range]	14 [0, 1848]	7 <sup>A</sup> [0, 1848]	30 <sup>B</sup> [0, 1848]
Median duration of enforcement process in days [range]	57 [1, 1083]	41 <sup>A</sup> [1, 1083]	84 <sup>B</sup> [1, 1083]
Preceding request to correct violations before initiating an enforcement process had been given in % of violations (n/N)	65 (353/541)	52 (123/236)	75 (230/305)

<sup>a</sup> Violations categorized as critical were related to traceability, temperature control, cleanliness of equipment or surface in contact with food, operational or personal hygiene, hand-washing and personal hygiene facilities, and food quality and safety.

<sup>A, B</sup> Different capital letters indicate a significant difference between critical and non-critical violations (Mann-Whitney U test,  $p < 0.001$ ).

Recurrent use of enforcement measures due to repeated violations was needed in 16% (85/541) of the violations, which were most commonly categorized as non-critical, e.g. deficiencies in self-checking systems, infrastructure or other non-compliance such as improper labelling (I). The authority reported food regulation offences to the police in 6% (12/188) of all cases. Of these cases, 67% (8/12) resulted in a fine given to the FBO and 8% (1/12) in a fine with conditional imprisonment. In the rest of the reported cases, the outcome of the investigation was unclear or the investigation was unfinished.

Among the D-graded cases in 2014 (III), the FBOs corrected the D-graded non-compliances already during the inspection visit in 19% (14/75) of the cases and by the end of 2015 at the latest in 64% (48/75) of the cases. In the rest of the cases, the FBO changed or ceased the operations (12%; 9/75) or the non-compliances were not corrected during the study period (5%; 4/75). If not corrected during the inspection but corrected by the end of 2015, the non-compliances were corrected by the first follow-up inspection in 63% (30/48) of the cases. In the remaining cases, two to five follow-up inspections were required. When an enforcement process was initiated ( $n = 29$ ), the non-compliances were corrected or the FBO ceased the operations already during the hearing process in 45% (13/29) of the cases.



### **5.3.2 INFLUENCE OF OFFICIAL FOOD CONTROL ON OPERATIONS OF FBOS (IV)**

When asked about their opinions of the influence of official food control on the hygiene in their establishment, 67% (82/122) of the FBOs stated that the food control official noted relevant food safety issues and the establishment corrected the operations significantly or to some extent. According to nearly all of the responding FBOs (95%; 127/133), the official “always” or “most often” ensures that food safety violations are corrected, and for 79% (103/130) of the FBOs, time limits for correction of violations had been set. No significant differences in these responses occurred between establishments grouped by size or main type of production. However, only slightly over half of the FBOs considered that the control actions have been effective, and even fewer perceived that the received benefits correspond to its costs (Figure 1). Among the responses regarding the efficacy of control actions and the benefits of official food control, significant differences were observed among FBOs grouped by the size of establishments (Pearson Chi-square exact test,  $p < 0.005$ ) (Figure 1). Small-sized FBOs were particularly pessimistic about these topics, as only 28% (5/18) agreed that the control actions have been effective, and 55% (11/20) disagreed that the benefits received correspond to the costs of official control. The means of the sum variable created for the school grades given by the FBOs to the quality of official food control were also lower among small FBOs than among other establishments (Kruskal-Wallis test,  $p = 0.033$ ). The means of the sum variable correlated positively with the opinions of FBOs on whether the control actions of the official had been needed, effective or prevented future non-compliance (Spearman’s rho,  $r = 0.421$ ,  $p < 0.001$ ;  $r = 0.581$ ,  $p < 0.001$ ; and  $r = 0.472$ ,  $p < 0.001$ , respectively).

Of the FBOs, 66% (78/118) considered that a good hygiene level resulting in reduction of control fees of the establishment would “very positively” or “somewhat positively” influence hygiene maintenance.

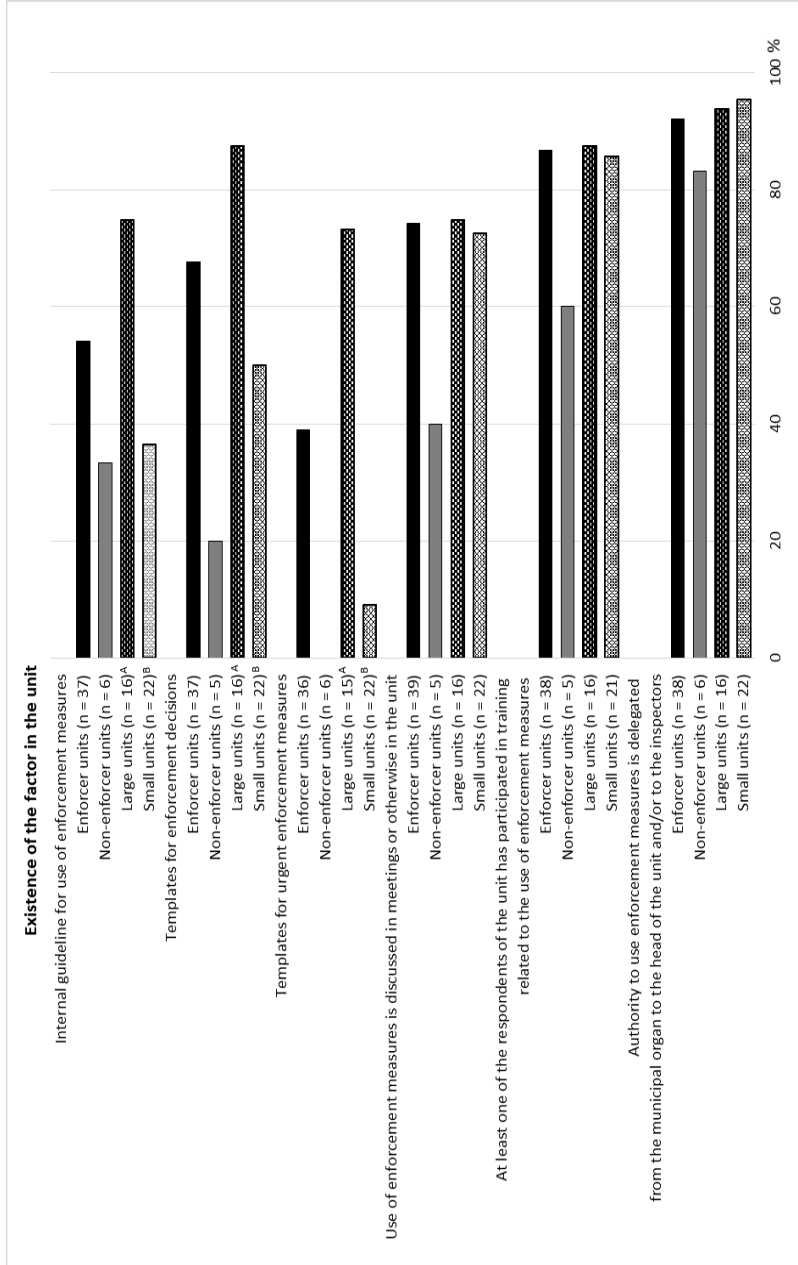
## **5.4 CONSISTENCY OF ENFORCEMENT (II-IV)**

### **5.4.1 PRACTICAL PREREQUISITES AND ROUTINE FOR USING ENFORCEMENT MEASURES IN THE UNITS (II, III)**

Based on survey responses, enforcer units had significantly higher scores (median 0.67, mean 0.71, range 0.17-1.00) than non-enforcer units (median 0.33, mean 0.37, range 0.20-0.50) (Mann-Whitney U test,  $p = 0.001$ ) (II). The scores were also significantly higher in large units (median 0.83, mean 0.82, range 0.17-1.00) than in small units (median 0.50, mean 0.58, range 0.17-1.00) (Mann-Whitney U test,  $p = 0.002$ ). The scores of the units did not differ regionally (Kruskal-Wallis test,  $p = 0.696$ ). Of the sole factors used in scoring the units, an internal guideline and templates for enforcement decisions and

urgent enforcement measures existed significantly more often in large units than in small units (Figure 3). In the enforcer units, all factors existed more often than in non-enforcer units, although the differences were not statistically significant (Figure 3). However, certain practical tools needed for the use of enforcement measures were also lacking in many enforcer units (Figure 3), and up to 40% (40/100) of the respondents of enforcer units perceived their unit not to have routine practices in the use of enforcement measures. Judicial assistance for the use of enforcement measures was available in 54% (15/28) of the units, based on the responses of the heads of the units. All of these units were enforcer units.

Also the interviews of the officials revealed variation and discrepancies in responses regarding practices and policies; for instance, in 33% (5/15) of the units, the officials provided inconsistent opinions on whether or not their unit has a guideline for the use of enforcement measures (III). When asked about their views on the common policy in their unit regarding the use of Oiva grades and enforcement measures, 11/36 interviewed officials in 8/15 units stated that a grade C may be given one to three times before giving a grade D and initiating an enforcement process. In six units, at least one official mentioned that the grade and the initiation of an enforcement process are deliberated case-dependently, and in five units, that their unit has no joint policy on the subject. In four units, some of the answers indicated that giving a grade D may be avoided to circumvent the use of enforcement measures. In one unit, however, all three interviewed officials emphasized the clear practices and experience of the head and officials of their unit in using enforcement measures.



**Figure 3.** Existence of factors related to the use of enforcement measures in the local food control units used in scoring the units, grouped by the use of enforcement measures in the last three years and size of the units (II).  
<sup>A, B</sup> Different letters indicate a significant difference between large and small units (Fisher's exact test,  $p < 0.005$ ).

#### **5.4.2 EXPERIENCE AND EXPERTISE OF OFFICIALS IN USING ENFORCEMENT MEASURES (II)**

Most officials agreed that the enforcement procedure is laborious, and many stated that using enforcement measures is difficult (Figure 2). The arduousness of the process and uncertainty in the use of enforcement measures arose as themes also in the content analysis of the answers to two open-ended questions regarding the use of enforcement measures and related challenges (Table 6).

Of the inspectors, the majority perceived their own knowledge of food hygiene and safety (87%; 85/98) and food safety legislation (88%; 85/97) as adequate for the use of enforcement measures. However, expertise in administrative procedures and certainty in using enforcement measures appeared to be perceived as somewhat lower by non-enforcer than enforcer inspectors. Of enforcer inspectors, 82% (51/62) “fully” or “partly” agreed that they have sufficient knowledge of administrative procedures, and 89% (55/62) “fully” or “partly” agreed that it is clear to them when using enforcement measures is reasonable. By contrast, the corresponding proportions among non-enforcer inspectors were 64% (23/36) and 74% (26/35), although the differences between enforcer and non-enforcer inspectors did not reach statistical significance (Fisher’s exact test,  $p = 0.053$  and  $p = 0.088$ , respectively).

The vast majority of all inspectors (92%; 87/95) “fully” or “partly” agreed that they would get support from the head of their unit in using enforcement measures. However, the inspectors of enforcer units assessed the expertise of the head of their unit considerably more positively than did the inspectors of non-enforcer units. In the opinion of the inspectors of enforcer units, the head of their unit has sufficient knowledge of food hygiene and safety (97%; 83/86), food safety legislation (95%; 81/85) and administrative processes (99%; 85/86). Among the inspectors of non-enforcer units, the corresponding shares of these three sectors were 14% (1/7), 33% (2/6) and 43% (3/7) (Fisher’s exact test,  $p < 0.001$ ,  $p < 0.001$  and  $p = 0.010$ , respectively).

Among the inspectors, a significant difference was observed in participation in training related to the use of enforcement measures; 77% (47/61) of the enforcer inspectors, but only 39% (14/36) of the non-enforcer inspectors had participated in training within the last five years (Fisher's exact test,  $p < 0.001$ ). Of all officials, only 44% (49/112) considered available training for the use of enforcement measures to be sufficient. Moreover, only 52% (34/65) of the officials who had utilized the guideline provided by Evira considered the guideline as “very” or “quite” useful in practice.

**Table 6.** *Themes and subcategories that emerged in the content analysis of the answers (n = 73) of food control officials regarding the use of enforcement measures, the enforcement process and related challenges, based on the two open-ended questions: “Is there something you perceive as problematic, difficult or laborious in the use of enforcement measures?” and “You may freely express your opinions about enforcement measures.” (II).*

<b>Theme</b>	<b>Subcategories within the theme (frequency)</b>
Necessity of enforcement measures	Enforcement measures are important to official food control (12) Enforcement measures are sometimes “the only choice” (2)
Inefficiency of the process	The process is slow (14) Negotiation and discussion are preferable (10) Lack of substantial consequences to a non-compliant FBO (7) Fining the FBO should be considered an option (5) Using enforcement measures only as a last means (2)
Arduousness of the procedure	The administrative process is laborious and complex (26) The process is time-consuming (14)
Uncertainty in the use of enforcement measures	Formulating and reasoning of the decisions (19) Lack of routine and common practices (17) Need for more guidelines and training with a practical approach (10) Deciding which situations warrant an enforcement measure and which measures should be used (10)
FBO-related challenges	FBO’s lack of understanding of the enforcement decision, poor attitude towards compliance or inadequate knowledge of food safety (12) Difficulties in delivering the decision to the FBO (4) Language or cultural barrier (4)

### **5.4.3 OFFICIAL-FBO INTERACTION INFLUENCING THE EXPERIENCE OF ENFORCEMENT (II-IV)**

The expertise of the official was considered to be sufficient in the opinion of 71% (89/126) of the responding FBOs, and 64% (82/129) of the FBOs thought

that the official was adequately conversant with the operations of the establishment (IV). Moreover, 94% (120/128) of the FBOs stated that high-quality guidance given by the official has a “very positive” or “somewhat positive” influence on maintenance of the hygiene level of their establishment. Of the FBOs, 60% (79/132) “always” or “most often” contacted the official when they needed advice on food hygiene issues. Although only one-third of all FBOs wished to negotiate more with the official about the changes required in their establishments (Figure 1), up to 67% (12/18) of the small-sized FBOs wished for more negotiation.

A majority of the FBOs (81%; 109/134) perceived the co-operation with the official as “very good” or “good”, whereas 16% (22/134) considered it to be “neutral” and 2% (3/134) “poor” or “very poor”. FBOs’ perceptions of the co-operation correlated positively with the means of the sum variable created for the school grades given for official food control (Spearman’s rho,  $r = 0.601$ ,  $p < 0.001$ ). In addition, the views on co-operation correlated positively with the perceptions of the control measures being in line with observed non-compliance, being effective and yielding a good cost/benefit ratio (Spearman’s rho,  $r = 0.580$ ,  $p < 0.001$ ;  $r = 0.398$ ,  $p < 0.001$ ;  $r = 0.409$ ;  $p < 0.001$ ). Moreover, the perceptions of co-operation correlated negatively with the opinions of FBOs on whether official food control has been arbitrary (Spearman’s rho,  $r = -0.492$ ,  $p < 0.001$ ). Among the FBOs who saw the co-operation as “very good” or “good”, 92% (99/108) stated that the food control official focuses on relevant subjects during the inspections and 53% (57/107) considered the optimal inspection frequency to be the same as or more frequent than the current one, while the corresponding shares among the FBOs perceiving the co-operation as “very poor”, “poor” or “neutral” were 40% (10/25) and 21% (5/24) (Fisher’s exact test,  $p < 0.001$  and  $p = 0.006$ , respectively).

According to the responding officials (II), 79% (27/34) of the non-enforcer inspectors “fully” or “partly” agreed that using enforcement measures would impair the co-operation between the inspector and the FBO, compared with 56% (33/56) of enforcer inspectors (Fisher’s exact test,  $p = 0.026$ ). FBO-related reasons also emerged as a theme in the open answers (Table 6). In the interviews of the officials (III), a co-operative attitude of the FBO or attempts to comply were also mentioned by a few officials as reasons for preferring negotiation instead of using enforcement measures.

#### **5.4.4 INFLUENCE OF OIVA EVALUATION GUIDELINES ON USE OF ENFORCEMENT MEASURES (III)**

Most officials responding to the questionnaire perceived that the Oiva evaluation guidelines provide unambiguous criteria for using enforcement measures (69%; 87/126) and enable better prerequisites for consistent use of enforcement measures within their unit (76%; 88/116) and between the units (71%; 85/119). Of the officials from enforcer units, 49% (55/113) thought that the Oiva system has “clearly” or “somewhat” lowered the threshold for using

enforcement measures in their unit, 45% (51/113) perceived no change and 6% (7/113) perceived the threshold to have “clearly” or “somewhat” risen.

The Oiva system clarifying the criteria for initiation of an enforcement measures was also noted by seven officials in the elaborating open comments (n = 17). However, differing policies between the units were stressed by three respondents, and two stated that consistency within the unit depends not on the Oiva system but on the practices of the unit. Furthermore, discretion on a case-dependent basis and always taking into account the nature of the non-compliance was emphasized by four respondents who stated that giving a grade D does not automatically require the use of enforcement measures. Moreover, publication of inspection results was perceived to enhance the correction of non-compliances, thus decreasing the need for using enforcement measures, according to two officials.

Figure 4 summarizes the factors influencing the use of enforcement measures and is based on Studies II and III.

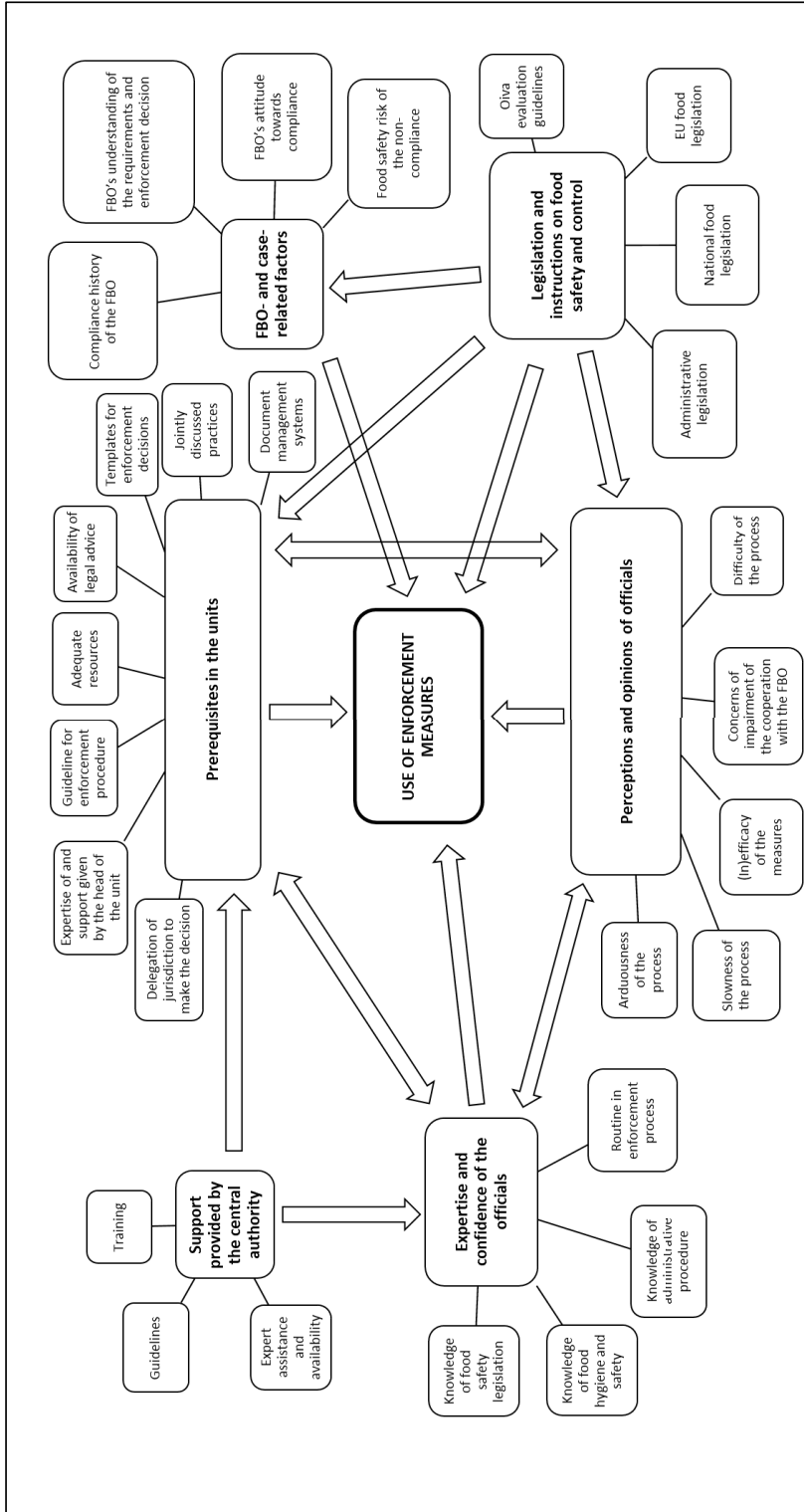


Figure 4. Factors influencing the use of enforcement measures in local food control (II, III).



#### **5.4.5 CONCERNS OF FBOS REGARDING THE CONSISTENCY OF CONTROL AND THE OIVA SYSTEM (IV)**

Nearly all (90%; 121/134) of the responding FBOs agreed that official food control should be uniform. However, only 36% of the FBOs considered it to be such, and 23% stated that official food control has been arbitrary (Figure 1). Of the small-sized FBOs, 47% (9/19) perceived the control to be arbitrary. In their answers to two open-ended questions (n = 72), the FBOs defined uniformity of official food control to mean similar rules, requirements and instructions for all FBOs (n = 39) and “consistent treatment” despite the location of the establishment (n = 27) or the interpretation of the official (n = 20). On the other hand, taking the size of the establishment and the nature of its operations better into account in, for instance, risk assessment, control fees and sampling requirements, was mentioned in 24 answers.

The attitude of most responding FBOs towards the Oiva system was positive (42%; 51/121) or neutral (31%; 38/121), but 26% (32/121) reported a negative attitude. Only 57% (64/113) of the FBOs “fully” or “partly” agreed that the Oiva system increases uniformity of official food control, but up to 41% (45/109) “fully” or “partly” agreed that the Oiva system makes official food control stricter than before. Moreover, among the establishments that had been inspected according to the Oiva system (n = 87), only 24% (19/78) believed that the Oiva system would enhance the correction of violations in their establishment. Less than half (49%; 35/71) of the FBOs in this group of respondents believed that the Oiva grades matter to their customers, and an even smaller proportion (34%; 24/70) considered the grades to be important when choosing their suppliers or subcontractors.

A positive aspect is that 63% (49/79) of the FBOs with experience of the Oiva system agreed that the publicly available Oiva evaluation criteria disclose the issues that are the focus of the food control official during inspections and reveal how the observed violations are graded. However, the content analysis of the answers to the open-ended question (n = 42) regarding the Oiva system identified concerns related to injustice and necessity of the system as the main themes. The perceptions of injustice were revealed in the responses worrying about inspections focusing on irrelevant issues (n = 13), varying interpretations and even the arbitrariness of officials (n = 8), and the lowest grade of all areas inspected determining the overall grade of the whole inspection (n = 7). Additionally, the necessity of the Oiva system or its suitability in the food industry was questioned in eight responses, and six respondents doubted consumer understanding of inspection reports. The perception of the Oiva system increasing the costs of official food control was discussed in five responses. In two optimistic responses, however, the Oiva system and common guidelines were seen as an opportunity to harmonize official control.

## 6 DISCUSSION

### 6.1 RISK-BASIS OF ENFORCEMENT

Based on the results of this thesis, official food control has an important role in detecting food safety violations and encouraging FBOs to correct them. Severe or multiple non-compliances were reported in the enforcement decisions and graded as jeopardizing food safety in the Oiva inspection reports, although the current food safety legislation builds on the principle that FBOs are responsible for the safety of their operations and foodstuffs and have in-house control systems in place to ensure compliance (EU, 2004a).

Studies I-III indicate that local food control officials have an advisory attitude and enforcement measures are mainly used only when other actions have proved insufficient. This is supported by the findings that the FBO had been requested to correct the detected violations before using enforcement measures in most enforcement cases in Studies I and III. Moreover, the most commonly used enforcement measure was an order, which is juridically the mildest measure, whereas a stronger measure, prohibition, was mainly used with critical violations. The importance of negotiation and attempts to encourage compliance through softer measures also emerged in the responses of the officials in Studies II and III. These findings are in accordance with the principles of risk-basis, proportionality and progression of enforcement (EU, 2004d; OECD, 2014) and in line with findings of other studies reporting that officials primarily aim at advising the operators before applying stricter enforcement actions (Campbell et al., 2011).

Enforcement measures were used mostly in cases with multiple, repeated or critical food safety violations, indicating that the reasons for using enforcement measures are well justified. Many of the violations underlying enforcement measures or graded as D in the Oiva system, such as improper temperature control, insufficient prevention of cross-contamination or unhygienic working practices, are considered critical for food safety and prevention of foodborne outbreaks (Todd et al., 2007; Gormley et al., 2011; US FDA, 2013; EFSA & ECDC, 2016). Further, a more rapid progression to stricter control measures, a lower number of preceding requests to correct the violations and conducting the enforcement process more rapidly in critical than non-critical violations in Study I reflect a risk-based approach to enforcement. Assessing the food safety risk caused by the non-compliance was also stressed among the interviewed officials in deciding whether or not to initiate an enforcement process. Although not always reported as directly contributing to foodborne outbreaks, the most commonly reported non-compliances in the enforcement decisions in Study I – infrastructure of the premises, traceability of foodstuff, self-checking system or other non-compliance such as improper or misleading labelling – may endanger food

safety. Insufficient or faulty labelling may lead to serious health hazards in case of missing allergen information (Gowland & Walker, 2015), and deficient traceability can endanger tracing back of the foodstuff in, for instance, foodborne outbreak investigations (Lundén, 2013). Proper infrastructure and suitability of the premises build a basis for arranging operations in a hygienic way and preventing cross-contamination in the operations. Further, a food safety management system suited for the operations of food premises is essential for assessing critical control points in the operations, establishing jointly adopted working practices and orientating new employees. However, the significance of these food safety issues may not be obvious to all FBOs or their correction may be prohibitively expensive or require major changes in the operations, possibly explaining why FBOs fail to conduct the corrective actions and intervention by food control officials by using enforcement measures is needed. Financial constraints and a lack of food safety knowledge or understanding of the legislation are widely reported challenges of FBOs to comply with or implement food safety systems (Yapp & Fairman, 2006; Baş et al., 2007; Mensah & Julien, 2011; Nevas et al., 2013).

The responses of FBOs in dairy, fishery and meat establishments in Study IV suggest that they appreciate official food control and consider it to be important for the food safety of their establishment. Moreover, the high school grades given for official food control indicate a general satisfaction of FBOs with its quality. The time limits set by the food control official for correction of non-compliances and ensuring that they were corrected also demonstrate the necessity and efficacy of controls. The results are in line with previous studies reporting high appreciation of official food control and its importance among Finnish FBOs (Nevas et al. 2013; Lääkkö-Roto & Nevas, 2014b).

Although the perceptions by FBOs of official food control were generally positive, rather critical opinions of the relevance of the requirements and the risk-basis of local food control and the Oiva system were observed. Only 57% of the responding FBOs considered official food control to be risk-based, and the open answers implied that rather many FBOs wished that the size, type of production and nature of the operations of the establishment would be taken more into account in the control. The dissatisfaction with control was also indicated in the concerns of FBOs regarding the Oiva inspections focusing on irrelevant issues and half of the FBOs reporting that the optimal inspection frequency of their establishment would be less than the current frequency. Arguably, the extensive and detailed requirements set for approved establishments promote critique of official control. FBOs may also not understand the influence of the compliance history on risk assessment, as the majority believed that the control history of a FBO should not affect the control action taken, with the control actions being similar in all cases. It is also possible that the Oiva system in the approved establishments having just recently begun before conducting the survey explains the more guarded perceptions and concerns of FBOs regarding the risk-basis and justness of official food control in general. To promote the trust of FBOs on the risk-basis

of control, particular attention should be paid to explaining and justifying the inspection frequencies to the FBOs. Explicit communication and adequate reasoning of control actions and requirements also helps the FBOs to understand the relevance of the non-compliances and required actions (Nevas et al., 2013; Lääkkö-Roto & Nevas, 2014b).

A risk-based approach in enforcement is further emphasized both in the new EU regulation on official controls (EU, 2017) and in the national guidelines (Evira, 2017b), further enhancing the risk-based characterization of FBOs and their inspection frequencies. For instance, taking into account the existence and level of private quality systems and the results of audits in the determination of the frequency of official control has been incorporated in the new EU regulation on official controls (EU, 2017) and discussed during the preparatory work of reforming the Finnish Food Act (Haikonen & Miettinen, 2018). However, despite reported overlap between official inspections and private audits, a recent Finnish study indicates major differences in the findings made during official controls and private audits (Turku et al., 2018). For instance, non-compliances related to crucial food safety components, such as sanitation, prevention of cross-contamination and sampling, have been significantly more frequently detected during official inspections than during private audits (Turku et al., 2018), thus raising questions about the comparability of these two inspection modes.

## **6.2 EFFICACY OF ENFORCEMENT**

More than 40% of the responding officials in Study II perceived that enforcement measures are not always used in their unit when needed to assure food safety, indicating that the control is not always as efficacious as it should be. Moreover, FBOs having a history of non-compliance for several years and unsuccessful preceding requests to correct recurrent non-compliances before initiating an enforcement process in Studies I and III indicate that the advisory control measures are not always efficacious enough and enforcement measures have not in all cases been used as rapidly as they should have been. In some cases, enforcement measures were not used even though the FBO was given the poorest inspection grade repeatedly due to the same non-compliances. Not using enforcement measures when needed may set FBOs in an unequal position and, in the worst case, jeopardize food safety.

When used, enforcement measures appear to induce compliance and the officials consider them necessary control methods. In Study III, even a threat of enforcement measures and hearing the argumentation of the prospective enforcement decision accelerated the correction of violations in nearly half of the enforcement cases. Therefore, instead of recurrent inspections with poor results, smooth and rapid initiation of an enforcement process would be preferable and increase the efficacy of controls. However, the long durations

of pre-enforcement and enforcement processes and the recurrent need to use enforcement measures decrease the efficacy of enforcement. Also a notable number of the officials seem to be dissatisfied with the efficacy of using enforcement measures, perceiving them as laborious and slow. The long durations of the processes are partly explained by the required administrative stages of the procedure, but may also reflect uncertainty, insufficient guidance and unclear practices in the units.

The measures having a direct economic impact on the FBO appear to be efficacious. Each case in which a threat of penalty payment or a suspension of operations was imposed in Study I resulted in compliance. However, the enforcement processes in these cases took a long time, during which the violations persisted, thus decreasing the usability of the measures and the efficacy of the procedure. Imposing a penalty payment or a threat of suspension is a rather laborious process with several administrative steps that take time and resources. The slowness of the procedure probably explains why almost 60% of the responding food control officials in Study II agreed that a fine imposed by the head of the unit should be incorporated into enforcement measures. However, barely 40% agreed that the inspecting officials should have the right to impose on-site fines, indicating that the fining issue divides opinions of food control officials and would be a major change in the Finnish food control culture. For instance, in Denmark, an administrative fine can be imposed in response to non-compliance detected during an inspection (DVFA, 2015), and the possibility to issue on-site fines to FBOs has been discussed as an option to enhance the efficacy of control actions also in Finland (Lepistö, 2008). Recently, incorporating an administrative fine into the available enforcement measures has been discussed as a part of reforming the Finnish Food Act (Haikonen & Riipinen, 2017). Considering the observed inconsistencies in the current use of enforcement measures, ensuring the legal protection of FBOs would arguably be among the foremost challenges in imposition of fines in food control. The possibilities to simplify and quicken the enforcement process, without compromising the legal protection of FBOs, should be further investigated. Moreover, independent of the administrative enforcement procedure, a lower threshold of food control authorities in reporting severe food safety violations to the police could improve the deterrent aspect of official food control (Lepistö & Hänninen, 2011).

The need for more stringent rules and enforcement methods for non-compliant or fraudulent FBOs has been identified also at the EU level. The new Official Controls Regulation (EU) No 2017/625, becoming gradually applicable but in full in December 2019, amends several previous regulations and repeals Regulation (EC) No 882/2004 and Regulation (EC) No 854/2004 (EU, 2017). The new regulation further stresses a risk-based approach in control, extends the list of enforcement actions and reinforces the rules on financial penalties for fraudulent practices (EU, 2017).

Among the responding FBOs (IV), rather critical opinions of the necessity and efficacy of control actions in practice emerged. These findings somewhat

differ from those of a study on restaurant business operators, the majority of which perceived the control measures taken in their restaurants as needed, effective and preventative of future non-compliance (Läikkö-Roto & Nevas, 2014b). Also in a study on FBOs in approved establishments conducted in 2006, nearly 90% of the FBOs believed that the actions taken by the food control official had enhanced hygiene in their establishment (Nevas et al., 2013). Thereafter, food legislation has developed in an increasingly co-regulatory direction, placing more and more responsibility on the FBOs and their in-house control systems. In this study, FBOs assessed the hygiene level of their establishments as very high, which may explain why the actions taken by the control official might not be considered necessary or as having much effect on the operations. However, given the rather low response rates of the FBOs, it is possible that the respondents represent a particularly critical group of FBOs and the results may not be fully generalized. Moreover, the perceptions of FBOs of the food safety level of their establishments and the need for corrective actions may differ from that of the food control official; several studies have reported deficiencies in the food safety expertise of the FBOs or in their skills in evaluating the food safety risks in their operations (Clayton et al. 2002; Walker et al. 2003a; Baş et al. 2006; Jianu & Chiş 2012; Karaman, 2012; Nevas et al. 2013).

Interestingly, while most responding FBOs considered official food control to be important for the economic success of their company, the benefits of official food control were seen as minor relative to the costs. Presumably, most FBOs appreciate the role of official control in, for instance, preventing distorted competition between compliant and non-compliant FBOs. On the other hand, the concrete expenses of official controls, such as inspection fees and the costs of correction of certain non-compliances due to requirements by control officials, may cause dissatisfaction among FBOs. In addition, as rather few FBOs found the Oiva grades to be important for their business transactions, it may be that official control results are not perceived to be as valuable for business as, for instance, private certificates, thus affecting FBOs' perceptions of the cost/benefit ratio of official control.

### **6.3 CONSISTENCY OF ENFORCEMENT**

Variation in the use of enforcement measures was observed between the units as well as among the officials (I-III). Perhaps the units and officials who have used enforcement measures only rarely or not at all have had no need to use such measures. However, it appears that the variation also arises from differing practices and prioritization of control methods. Based on the results of Studies II and III, a lack of routine, uncertainty and unclear practices and alignments in the units hinder the use of enforcement measures and weaken the consistency of control. The low number of respondents from non-enforcer

units in Study II limits the comparison of the units, but possibly also leads to an underestimation of the differences between units and the difficulties related to using enforcement measures.

Reluctance to issue a grade D to avoid later use of enforcement measures, as stated by a few interviewed officials (III), may not only set FBOs in unequal positions but also compromise food safety. Variation in assessment of non-compliances and a narrow use of the grading scale may also weaken the transparency and relevance of information provided in disclosure of the inspection results (Ho, 2012). Varying interpretations by the local food control officials regarding an adequate level of compliance and the needed control actions (Läikkö-Roto et al., 2015) and defective adoption of and commitment to joint practices in the units (Läikkö-Roto et al., 2016) have been earlier reported in Finnish local food control. Also in other regulatory areas, such as occupational safety and health, factors related to the experience of the officials and insufficient instructions have been identified as hindering the efficacy and consistency of enforcement (Niskanen, 2015).

Only about one-third of the responding FBOs in Study IV considered official food control to be uniform, and one-fifth reported that it was arbitrary, demonstrating strong dissatisfaction with the consistency and fairness of official food control. Differing interpretations between officials and excessive power of a single food control official in grading were particularly noted by FBOs in the comments related to the Oiva system. The findings of varying enforcement practices and opinions of FBOs of differing requirements among control units and inspectors are in line with previous studies reporting inconsistencies in enforcement between food control authorities (Hutter & Amodu, 2009; Mascini & Wijk, 2009; Ho, 2012; Lee-Woolf et al., 2015; Läikkö-Roto et al., 2015). The perceptions of inequity and injustice in the grading may also indicate FBOs' distrust of food control authorities. Traditionally, Finnish citizens have had at least a moderate trust in public sector institutions and organizations, but the realization of the principles of good governance, e.g. guidance given by the public authorities and clarity and understandability of administrative decisions, has garnered less satisfaction among citizens (Salminen & Ikola-Norrbacka, 2010). Among FBOs, a lack of trust in food control officials has been noted to hamper their compliance with food safety regulations (Yapp & Fairman, 2006).

## **6.4 IMPROVING THE BASIS FOR EFFICACIOUS AND CONSISTENT ENFORCEMENT**

### **6.4.1 DEVELOPING PRACTICAL TOOLS AND EXPERTISE IN THE UNITS**

The results of Studies II and III highlight the importance of practical prerequisites such as guidelines for the enforcement process, templates for decisions and jointly discussed alignments in facilitating the initiation of an enforcement process and increasing the consistency of practices. Also previous studies have recognized the benefits of checklists and pre forma templates for inspection reports in increasing the efficacy and consistency of controls (Läikkö-Roto et al., 2015) and the importance of proper orientation of the personnel in committing the personnel to joint practices (Läikkö-Roto et al., 2016). However, templates for urgent enforcement decisions, enabling immediate on-site initiation of an enforcement process, were available in less than half of enforcer units. Further development of simple templates for enforcement decisions could help in increasing the speed and efficacy of the enforcement process.

The size of the unit appears to be associated with the existence of practical prerequisites. In Study I, the number of enforcement cases did not correlate with the number of food premises in the areas of the units or with the labour resources of the units. However, based on the survey in Study II, larger units had used enforcement measures more commonly than the smaller ones and appeared to have better availability of practical tools for using enforcement measures. The prospective reform of organizing official food control in larger counties may thus promote certain prerequisites for efficacious enforcement such as possibilities of the counties to allocate labour and expertise for development of operational procedures and quality systems, opportunities for the officials to specialize in certain areas and resources to conduct co-inspections and develop peer-review systems. Adequate and easily available judicial assistance in enforcement procedures is also important, as the responding officials indicated the need for lawyers acquainted with food legislation in their unit.

Participation in training related to the use of enforcement measures differed significantly among enforcer and non-enforcer inspectors. Much effort has been directed to improving the skills of officials by providing new guidelines and more training, which have been reported to positively influence the use of enforcement measures (COM, 2013). Nevertheless, the responses of the officials indicate that the availability of the training provided is inadequate. Furthermore, non-enforcer inspectors displayed less certainty in deciding when enforcement measures should be used and assessed their knowledge of administrative procedures somewhat less positively. As previous studies have identified shortcomings in the implementation of administrative procedures and fulfilment of good governance among Finnish food control authorities



(Lepistö, 2008; Lepistö et al., 2009), further training on the administrative procedure, deciding which situations warrant enforcement measures and which measures should be applied and formulating and reasoning of the enforcement decisions appears to be needed. Targeted and frequent training with a practical approach and example cases would not only enhance the abilities of officials in using enforcement measures but also help in increasing the efficacy of the enforcement procedures and improving consistency of practices. Also other authors have reported that public health inspectors have expressed the desire for regular training on food safety and possibilities to share experiences with other officials (Pham et al., 2012).

Based on the responses of FBOs in Study IV, expertise of the official is valuable in motivating their compliance, as high-quality guidance from the official would positively influence the maintenance of the hygiene level of the establishment. Earlier studies have reported that officials are an important source of information on food hygiene and legislation for FBOs (Nevas et al., 2013), and satisfaction of the FBOs with the quality of official food control promotes their perceptions of its relevance and importance (Läikkö-Roto & Nevas, 2014b). Therefore, to guarantee high-quality guidance and support provided to FBOs, presumably enhancing the correction of non-compliances and improving food safety, regular maintenance and development of the expertise of the officials should be ensured.

The responses of Study II indicate that inspectors are satisfied with the expertise of and the support received from the head of their unit. However, inspectors of enforcer units assessed the expertise of the head more positively than did inspectors of non-enforcer units. These findings suggest that the food safety knowledge of the head of the unit and her/his conversance with enforcement procedures may promote the capabilities of inspectors in using enforcement measures and should therefore be ensured in all units. Also management skills of the head of the unit are essential in committing the personnel to quality systems and jointly agreed practices and promoting the efficacy of control (Läikkö-Roto et al., 2016).

Despite the identified challenges in the use of enforcement measures, the results of Studies I, II and III indicate that certain units have a particularly strong expertise and routine in using enforcement measures. Sharing of the good practices of these units could benefit the units with less experience in using enforcement measures. Moreover, increasing joint discussions on the alignments and interpretations of the requirements among the units could improve the consistency of enforcement practices. As the national audit system appears to have failed in providing the local officials with the practical evaluation and guidance needed, cross-audits among the units or including local officials in the audit teams has been suggested (Läikkö-Roto & Nevas, 2014a).

#### **6.4.2 ENHANCING CO-OPERATION BETWEEN THE OFFICIAL AND THE FBO**

Most FBOs perceived that the food control official focuses on relevant subjects during the inspections and agreed that they contact a food control official when in need of advice on food hygiene issues. Official-FBO interaction emerged as an important factor in supporting compliance, as the perceptions of FBOs of good co-operation with the official promoted their positive views of official food control and its quality, relevance and benefits. Experience of good co-operation and high-quality control had also a positive influence on the satisfaction of FBOs with the current inspection frequency, highlighting the significance of a collaborative approach to improve their perceptions of the relevance of official control and inspections. Moreover, a co-operative and communicative attitude is widely identified to strengthen common trust between officials and regulated parties (May & Wood, 2003; Pautz, 2009, 2010; Rorie et al., 2015; Meyer et al., 2017) and support compliance (e.g., Fairman & Yapp 2005; Green & Kane, 2014; Lääkkö-Roto & Nevas, 2014b; Buckley, 2015). The importance of communication is also demonstrated by Davies et al. (2014) who found unsuccessful communication to be associated with many experiences by FBOs of inconsistent control. However, despite the intentions of officials to communicate in a constructive way and be co-operative, other authors report that FBOs tend to perceive the behaviour of the official as more negative and coercive than intended by the official (Mascini & Wijk, 2009). Investing in training on communication and co-operative skills of the officials would therefore be beneficial in improving their abilities to perform in difficult and even coercive control situations and to promote positive attitudes of FBOs towards official control, motivation to comply with food regulations and trust in food control authorities.

Maintaining a good relationship with the FBO appears to be important for officials, as many of them were concerned about impaired co-operation as a consequence of using enforcement measures. This fear was found to be particularly strong among non-enforcer inspectors and may diminish their eagerness to use enforcement measures, possibly leading to unequal treatment of FBOs and inefficacious enforcement. Clear practices within the unit and enforcement measures being an ordinary part of control actions could mitigate these concerns. However, a concern about limited understanding of FBOs regarding the requirements and enforcement decisions, due to a lack of knowledge, poor attitude or cultural and language-related challenges, was also stated by some of the responding officials. Particularly small-sized FBOs do not necessarily have the competence to distinguish the legislative difference between administrative decisions and other documents received from authorities (Fairman & Yapp, 2005). The difficulties related to language barriers between officials and FBOs and the need for provision of food safety information in different languages to FBOs have also been previously reported (Pham et al., 2010b).

### **6.4.3 SUPPORTING OPERATING CONDITIONS OF FBOS**

The recurrence of non-compliances in Studies I and III, despite requests and enforcement measures applied by the control authorities, indicate that some FBOs lack the ability to manage food safety in their operations or have a poor attitude towards food hygiene and food safety rules. While the majority of Finnish FBOs are compliant and receive good or excellent inspection grades (Evira, 2017f), non-compliances and difficulties in managing food safety appear to accumulate with certain FBOs. Recurrent or certain food safety violations are associated with an increased likelihood of food premises being a source of foodborne outbreaks, thus creating a serious public health risk (Kassa, 2001; Petran et al., 2012). Detection of FBO-related factors that may predispose to recurrent non-compliant behaviour or difficulties in understanding food safety requirements, for instance, through a tool assessing food safety culture of the company (FSA UK, 2012) could help in risk-based targeting of rapid early-stage assistance and efficacious intervention in the operations of these FBOs.

The results of Study IV reveal variation in the opinions of FBOs regarding the relevance and uniformity of control in relation to the size of the establishment, but not in relation to the establishment's main type of production. The vast majority of the responding establishments were classified as SMEs based on their number of employees, and most were micro-sized, corresponding to the share of micro-FBOs in the Finnish food industry (Hyrylä, 2016). The low number of respondents in the categories limits the reliability of the comparison of groups, but small-sized (10-49 employees) FBOs appeared to be particularly critical of the relevance, quality and efficacy of official food control, compared with all other-sized groups. The strong perceptions of arbitrariness by this group of FBOs and their wishes for less frequent inspections and more negotiation about the required changes suggest that they have certain characteristics that make them perceive official food control as less fair or reasonable. Compared with larger FBOs, small FBOs may have a limited capacity to implement advanced food safety management systems, as a lack of resources, time and food safety expertise are widely reported challenges among smaller FBOs (Walker et al., 2003b; Fairman & Yapp, 2004; Yapp & Fairman, 2006; Violaris et al., 2008; Wilcock et al., 2011; Karaman, 2012). In addition, due to a lack of knowledge of legal requirements, particularly smaller FBOs may have a lesser ability to assess their own compliance (Fairman & Yapp, 2005). On the other hand, compared with micro-sized establishments that have very small-scale food processing, the nature and volume of the operations of small establishments may create substantially greater risks. Small FBOs may thus bear rather frequent inspections and strict interpretation of the requirements, explaining why the group of small FBOs appeared to perceive the burden and justness of official control pessimistically.

Among restaurant business operators, the hygiene level in their food premises appears to be positively associated with their knowledge of and

attitude towards food hygiene and official food control (Läikkö-Roto & Nevas, 2014b). Sufficient and regular food safety training provided to FBOs and their personnel could thus enhance their capability of detecting food safety risks in their operations and also enable them to gain the most benefits from inspections and the advice given by the food control official. To respond to the special needs of SMEs, Evira has recently launched a project to reform the public guidance system for small- and medium-sized food businesses (Evira, 2017a). The project also aims to take the special characteristics of FBOs with diverse cultural backgrounds better into account by providing them with special support such as translated guidelines on implementation of legislative requirements (Evira, 2017a). Moreover, as the competence of the officials to communicate with customers from diverse cultural backgrounds is essential for effective and equal delivery of services (Rice, 2007), this topic should be addressed in vocational education and further training of food control officials. A focus of future research should be to determine what FBOs expect from official food control and how the perceptions of FBOs regarding the benefits of official food control could be improved.

#### **6.4.4 ESTABLISHING THE OIVA EVALUATION SYSTEM AND STRENGTHENING THE TRUST OF FBOS IN THE SYSTEM**

The Oiva system and the evaluation guidelines appear beneficial in enhancing the risk-basis, efficacy and consistency of enforcement. However, as the system was in its early stages while Studies II-IV were conducted, its influence on the harmonization of control practices could not be comprehensively assessed. The findings of this thesis indicate that the guidelines as well as publicly announcing inspection results have the potential to speed up the enforcement process and correction of violations, although the data do not enable direct comparison of control actions employed before and after launching of the Oiva system.

To ensure consistent interpretation and practices, regular education of inspecting officials and detailed guidelines have been provided already before and since the introduction of the Oiva system. However, unification of the practices of many individual control units and inspectors are not simple processes and require continuous training and support be provided to the officials (Läikkö-Roto, 2016). In improving the consistency of evaluation and interpretation, peer-review and co-inspections among the inspecting officials are reported to be beneficial and have been recommended for inclusion in the standard practices of all food control jurisdictions (Ho, 2017).

The concerns of FBOs in Study IV regarding the justness of the system and its value for the food industry or consumers and their suspicions about the ability of the system to improve the consistency and efficacy of official control indicate rather low acceptance of the system among FBOs. As consumers usually do not directly deal with the approved establishments the same way as with retail stores or restaurants, FBOs may not perceive the disclosure of their

inspection results as useful. FBOs may also have a fear of the system creating negative publicity, indicated by the concerns of unfairness of the determination of the overall grade of the inspection based on the poorest grade of inspected items. Although the positive effects of disclosing the inspection results of retail food premises on consumer information and compliance are widely recognized (Jin & Leslie 2003; Simon et al., 2005; Thompson et al., 2005; Serapiglia et al. 2007; Filion & Powell, 2009; Ho, 2012; Papadopoulos et al., 2012; Djekic et al. 2014; Wong et al., 2015; Da Cunha et al. 2016a), no evidence yet exists about the influence of the system on food safety among FBOs operating before the retail stage. In addition, consumers may have a narrow understanding of the safe food handling practices and risks involved (Altekruse et al., 1996; Jevšnik et al., 2008a), thus having a limited ability to judge the meaning of different inspected items or grades. Consumers may also have misconceptions of the information presented in the inspection reports (Nielsen, 2006; Jones & Grimm, 2008; Leisner et al. 2014). However, considering that a majority of the Oiva grades of the approved establishments in 2015 were excellent or good (Evira, 2016a, 2016e), most of the FBOs appear to benefit from the system. More research is required to reveal the influence of the Oiva system on the operations of FBOs and whether FBOs' acceptance of the system and grading improves through solid establishing of the system. In developing the Oiva system further, particular attention should be paid to the risk-basis of the evaluation and grading criteria by monitoring the ability of the system to enhance the correction of violations and prevent public health risks. In addition, as Study III revealed challenges in assessing the use of enforcement measures on the basis of the data reported from the units in the national database, introducing the new data collection system for environmental health and food control (Evira, 2017c) will likely further improve the utilization of nationally collected data in developing the Oiva system and in evaluating the efficacy of food control actions.

## 7 CONCLUSIONS

The results of this thesis indicate that official food control has an important role in detecting food safety non-compliances, inducing their correction and supporting compliance in food premises. Despite the generally risk-based approach to enforcement, certain deficiencies in efficacy and consistency of enforcement practices were detected.

1. Administrative enforcement measures are necessary control methods to induce FBOs to correct food safety violations. Enforcement measures are mainly used when an FBO has multiple, recurrent or critical non-compliances and milder control measures have proved ineffective, indicating a risk-based and progressive approach to enforcement. The risk-basis is indicated also by the finding that the enforcement process is initiated more rapidly and the duration of the enforcement process is shorter in critical food safety violations than in non-critical ones.
2. The use of administrative enforcement measures leads to correction of non-compliances, but repeated requests to correct non-compliances before initiating an enforcement process and the long durations of enforcement processes decrease the efficacy of enforcement. Food control officials perceive the enforcement process as laborious and slow and are not fully content with the efficacy of the process. Repeated violations also indicate recklessness of some FBOs towards food safety requirements and raise the question of the need for more efficacious and rapid enforcement methods. A lower threshold for initiating an enforcement process and improving the speed and fluency of the process could increase the efficacy of enforcement by accelerating the correction of violations.
3. The approaches and preparedness to use enforcement measures vary among local food control units and among inspecting officials. Some units have well-established practices and routines in using enforcement measures, while other units apply enforcement measures rather infrequently or not at all. Case-dependent and risk-based discretion is required to find the most appropriate and efficacious way of intervening in non-compliant operations. However, inadequate practical prerequisites and unclear alignments in the units create uncertainty in using enforcement measures among the officials and decrease the efficacy and consistency of enforcement. Learning from the good practices of the units with a strong routine in using enforcement measures, further training of officials with a practical approach and

improving guidance are needed to overcome the hurdles to applying enforcement measures and to bolster the confidence of officials in their use.

4. FBOs in approved dairy, fishery and meat establishments appear to appreciate official food control and its importance for food safety. The quality of control is considered to be generally good and official food control is seen as having a positive influence on the hygiene level of most establishments. However, the consistency of official food control is perceived as rather poor, and particularly small-sized FBOs are critical of the relevance of the requirements and control actions in practice. A perception of good co-operation with the official is associated with positive views of FBOs about official food control, thus having a positive influence on the efficacy of enforcement and food safety.
5. The Oiva system has potential to standardize the use of enforcement measures. Improving the consistency of grading and enforcement practices is an ongoing process, in which further co-operation and peer-review between and within units would be beneficial. Among FBOs, the Oiva system appears to raise early-stage concerns regarding its suitability in approved establishments and the justness of the grading. As the system was in its early stages while this work was conducted, further research and more experiences with the system are needed before determining its influence on the efficacy of enforcement and the benefits provided to FBOs.

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