Consistency and risk-basis of using administrative enforcement measures in local food control

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Abstract

Consistency and risk-basis are core elements of effective enforcement of food safety legislation. In Finland, inspections of food retail premises have been conducted since 2013 based on new national guidelines for evaluation and grading. According to the guidelines, food control authorities should initiate an administrative enforcement process to ensure compliance if the food business operator (FBO) is given the poorest grade in the inspection. In this study, we examined the consistency within and between local food control units on the threshold of initiating an enforcement process. The study was conducted through an analysis of inspection reports of FBOs and by an electronic survey and interviews of local food control officials. The results reveal that most officials consider the national evaluation guidelines as helpful in improving the consistency of using enforcement measures. However, inconsistencies exist between and within the local food control units in the alignments of initiating an enforcement process. Enforcement measures are mainly used on a risk-basis and gradually, as in most enforcement cases the FBO had multiple non-compliances and the FBO had been given a prior request to correct the non-compliance before initiating an enforcement process. The results, however, revealed rather weak compliance and repeated violations among some FBOs. Based on the observed persistence of non-compliances and the efficacy of enforcement measures in inducing compliance, a lower threshold of initiating an enforcement process towards FBOs with repeated violations appears beneficial in enhancing the correction of violations. Increasing the consistency of the enforcement process begins with unifying the practices within the local food control units by establishing clear procedures for enforcement and ensuring adequate orientation of personnel. Further strengthening of cooperation, peer-review and discussion on interpretations of required control actions between the units is needed for nationally consistent implementation of the evaluation and disclosure system and use of enforcement measures.

Keywords
Official food control; administrative enforcement measures; consistency; risk-basis; non-compliance

1. Introduction

Effective enforcement of food safety regulations is essential for ensuring food safety and protecting public health (WHO, 2013; OECD, 2014). Although the inspection results of food premises may not directly predict the occurrence of foodborne outbreaks (Jones, Pavlin, LaFleur, Ingram, & Schaffner, 2004; Petran, White, & Hedberg, 2012b) or be associated with other food safety indicators (Kjeldgaard, Stormly, & Leisner, 2010; Leisner et al., 2014), several studies highlight the importance of a well-functioning official food control system and efficacious control actions to prevent the risk of food safety hazards (Lundén, 2013; Pei et al., 2011; Tähkäpää, Maijala, Hörman, Poutiainen-Lindfors, & Korkeala, 2008). The detailed regulations and institutional frameworks for enforcement vary among countries, but the principles aiming at ensuring compliance of food business operators (FBOs) with food safety legislation are global (WHO, 2013). Official food control actions should be effective and consistent and the approach should be primarily advisory and negotiative (EC No 882/2004; Food Act, 2011). In case of severe or recurrent food safety violations, however, authorities should ensure compliance by taking stricter control actions, i.e. enforcement (coercive) measures (EC No 882/2004; Food Act, 2011).

A responsive enforcement approach, in which the enforcement actions are adjusted to the control history and behaviour of the business, is considered to be the most effective approach to promote compliance among regulated business (Ayres & Braithwaite, 1992; OECD, 2014; Yapp & Fairman, 2006). However, despite the recognised benefits of a responsive approach, inconsistency in enforcement practices is a problem (Ayres & Braithwaite, 1992; Mascini & Wijk, 2009). Also in the field of official food safety control, inconsistency is a widely reported issue (e.g., Hutter &
Amodu, 2009; Ho, 2012; Lee-Woolf, Bain, & Fell, 2015; Läikkö-Roto, Mäkelä, Lundén, Heikkilä, & Nevas, 2015; Pham, Jones, Sargeant, Marshall, & Dewey, 2010). Underlying reasons for inconsistent enforcement practices and inspection procedures in official food control have been discussed to be e.g. ambiguity in legislative requirements, various factors related to characteristics of control authority and the nature of the relationship between the official and the FBO (Hutter & Amodu, 2009; Läikkö-Roto et al., 2015; Mascini & Wijk, 2009).

The official food control of Finnish FBOs, excluding slaughterhouses, is organised and conducted at the local level in 62 municipal environmental health and food control units (hereafter ‘units’). The units operate independently within their areas, but are nationally supervised by the Finnish Food Safety Authority Evira (Evira) (Food Act, 2011). Previous studies have reported variation and inconsistency among the units in e.g. resourcing of food control, inspection practices, risk-based approach and use of administrative enforcement measures (Kettunen, Nevas, & Lundén, 2015, 2017; Läikkö-Roto et al., 2015; Tähkäpää et al., 2008).

Consistency of controls is a prerequisite for publishing inspection results (Griffith, 2005). Inspections of Finnish food premises have been conducted via a disclosure system, known as the Oiva evaluation system, since May 2013 in the food retail sector and since May 2015 in the food industry overall. The inspection results are expressed via smiley faces that range from an Oiva grade A (‘excellent’), B (‘good’), C (‘to be corrected’) to D (‘poor’) (Evira, 2013) (Table 1). In the retail sector, the inspection report must be provided at the entrance of the food premises or in another place easily accessible to customers as well as on the company internet pages (Evira, 2016a). The inspections are conducted using standardised, publicly available Oiva evaluation guidelines. The guidelines define the Oiva grade to be given to each inspected item and the control actions that the food control officials should take based on the severity and recurrence of the observed food safety violation (Evira, 2013). According to the guidelines, food control authorities should always initiate an administrative enforcement process (henceforth ‘enforcement process’) if
food safety is jeopardised or the consumer is considerably misled (grade D) (Table 1). An enforcement process should also be initiated 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 (Table 1).

Administrative enforcement measures (henceforth ‘enforcement measures’) available to Finnish food control authorities include such measures as giving an order to correct the non-compliance, prohibition of placing a food on the market, ordering a withdrawal of food from the market or restriction or suspension of operations (Food Act, 2011). The use of enforcement measures has been reported to be an important tool to ensure that FBOs correct severe or recurrent food safety violations (Kettunen et al., 2015). However, the lengthy and time-consuming administrative procedures decrease the efficacy and applicability of the measures (Kettunen et al., 2015, 2017). Moreover, officials’ uncertainty, shortcomings in their knowledge of administrative procedures and lack of routine have been reported to hinder the use of enforcement measures (Kettunen et al., 2017; Lepistö & Hänninen, 2011; Lepistö, Nevas, & Hänninen, 2009).

To our knowledge, the influence of the inspection result disclosure system or national-level evaluation guidelines on the use of enforcement measures has not been previously investigated. The aim of this study was to examine the consistency and risk-basis of initiating an enforcement process in local food control units in Finland.

2. Material and methods

2.1 Questionnaire

As a part of a questionnaire developed for a larger survey regarding the use of enforcement measures and related challenges (Kettunen et al., 2017), we investigated the opinions of local food control officials about the influence of the Oiva evaluation system on the use of enforcement
measures and its consistency within and between units. The electronic questionnaire was issued to the inspecting food control officials of all 62 Finnish local food control units as well as to the heads of these units in September 2015. The part of the questionnaire regarding the influence of the Oiva system on the use of enforcement measures included the following three claims: 1) The Oiva evaluation guidelines provide unambiguous criteria for using enforcement measures; 2) The Oiva evaluation guidelines provide better prerequisites for consistent use of enforcement measures within our control unit; 3) The Oiva evaluation guidelines provide better prerequisites for consistent use of enforcement measures between control units. These claims appeared on a four-point Likert scale (1 = fully disagree, 2 = partly disagree, 3 = partly agree, 4 = fully agree). The respondents were also asked if enforcement measures had been used in their unit in the last three years. Respondents of the units in which enforcement measures had been used were asked whether the Oiva system has had an effect on the threshold of using enforcement measures in their unit according to the following scale: the threshold has clearly lowered, has somewhat lowered, is the same as before the Oiva evaluation system, has somewhat risen or has clearly risen. In addition, respondents could elaborate on their answers to closed questions in the subsequent open-ended questions ‘Please clarify your answer if needed’.

2.2 Inspection reports

Within the areas of the 45 Finnish local food control units that responded to the electronic survey described above, we searched the national database of food control data to detect the food retail premises that had been given a grade D during an Oiva inspection in 2014, but in which no enforcement measures had been used based on reported data. The number of such food premises was 75, located in the areas of 15 units. Of these premises, 71% (53/75) were restaurants, including cafeterias and other food serving premises, and 29% (22/75) were retail stores. For these premises, we collected inspection reports of Oiva inspections from the introduction of the Oiva evaluation
system in May 2013 until December 2015 from the database. The inspected items that were graded as D in the Oiva inspection reports were categorised according to the 17 main categories of inspected items presented in the Oiva evaluation guidelines for notified food premises (Evira, 2016b).

2.3 Interviewing food control officials

An interview form was developed for the local food control officials (henceforth ‘officials’) who had conducted Oiva inspections of the 75 FBOs described above in 2014. The interviews were conducted by one author (SP) of the study via telephone between December 2015 and March 2016. The aim of the interview was to explore the factors related to the official, control unit and control history of the FBO that would have influenced the use of enforcement measures in those cases in 2014. In five cases, the official who had conducted the control actions was not available for interview; in these cases a colleague or superior of the official was interviewed.

The semi-structured interview form included questions in which the interviewees could choose from given alternatives and also contained open questions (see Appendix). The interviewees were asked whether, and if yes, which enforcement measures had been used in the cases and the reasons for not using enforcement measures despite the given grade D. Additionally, the interviewees were asked for their opinion about a possible jointly agreed unit-level alignment regarding the use of enforcement measures as a consequence of a grade D.

2.3 Data analysis

All data were processed using SPSS statistical software (IBM SPPS Statistics 22.0, NY, USA). In the analysis of the inspection report data, Fisher’s exact test was used to compare the compliance
168  history of the FBOs in 2013 and 2014 between the cases grouped based on initiating or not
169  initiating an enforcement process. Statistical significance was accepted with a confidence level of
170  95% (two-tailed $p$-values < 0.05).
171
171  In the analysis of the responses to the electronic questionnaire, the respondents were
172  grouped based on whether enforcement measures had been used in their unit within the last three
173  years. The comments to the open-ended questions ‘Please clarify your answer if needed’ about the
174  influence of the Oiva system on the initiation and consistency of an enforcement process were
175  systematically coded and categorised to identify patterns and themes in the data by using a method
176  of content analysis described by O’Cathain and Thomas (2004).
177
177  In the analysis of the interviews, the officials were stratified based on their units. In
178  analysing the responses to the electronic questionnaire and interviews of the officials, the ‘I don’t
179  know’ answers were categorised as missing.
180
180  3. Results
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182  3.1 Received responses, analysed inspection reports and conducted interviews
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183  Altogether 129 responses to the questionnaire were received from 73% (45/62) of the local food
184  control units. In 87% (39/45) of the units, enforcement measures had been used in the last three
185  years; the number of respondents from these units was 120.
186
186  The number of Oiva inspection reports analysed was 305. The total number of
187  inspections conducted on 75 FBOs in 2013-2015 was 394, of which 89 were excluded from the
188  analysis because they were related to e.g. projects or customer complaints or were for other reasons
189  not reported as Oiva inspections. Non-compliances graded as D were reported in a total of 12 main
190  categories of inspected items.
The number of interviewed officials was 42, ranging from one to seven interviewees per unit. Of the interviewed officials, 43% (18/42) had conducted inspections in more than one food premises included in the study.

3.2 Influence of the Oiva evaluation system on the use of enforcement measures

Based on food control officials’ responses to the electronic questionnaire, 69% (87/126) of the officials ‘fully’ or ‘partly’ agreed that the Oiva evaluation guidelines provide explicit criteria for using enforcement measures. A majority of the officials (76%; 88/116) also ‘fully’ or ‘partly’ agreed that the evaluation guidelines provide better prerequisites for consistent use of enforcement measures within their unit, and 71% (85/119) saw a similar effect between the units. Of the officials from the units in which enforcement measures had been used in the last three years, 49% (55/113) stated that the Oiva evaluation system has ‘clearly’ or ‘somewhat’ lowered the threshold for using enforcement measures in their unit. In this group of respondents, 45% (51/113) perceived the threshold to be the same as before the Oiva evaluation system, and 6% (7/113) responded that the threshold has ‘clearly’ or ‘somewhat’ risen.

In the open comments (n = 17) regarding the influence of the Oiva evaluation guidelines on the threshold or consistency of using enforcement measures, seven respondents stated that the Oiva evaluation system has clarified the criteria for the use of enforcement measures. However, four respondents highlighted that case-dependent discretion, taking into account the nature of the non-compliance, is always needed and that a grade D does not thus automatically lead to the use of enforcement measures. Three respondents also pointed out that the alignments differ among the units and two stated that consistency within the unit depends on the unit’s practices, not on the Oiva system. Two respondents noted that the disclosure of the inspection results has
enhanced the correction of non-compliances, thus decreasing the need for using enforcement measures.

3.3 Initiation of an enforcement process and non-compliances of FBOs

Although the use of enforcement measures was not reported in the national database, an enforcement process was nevertheless initiated in 39% (29/75) of the cases based on the interviews of the officials. In 16 of these cases, an enforcement decision was made, and in 13 of the cases, the FBO was heard on the prospective decision of using enforcement measures, but no enforcement decision was eventually needed because the FBO corrected the non-compliance as a consequence of the hearing process. An order was the most commonly used enforcement measure (94%; 15/16 cases). In 61% (46/75) of the cases, no enforcement process was initiated, but the food control official noted the non-compliance and requested its correction in the inspection report. In 44% (4/9) of the cases in which an FBO had been given a grade D repeatedly in 2014, no enforcement process was initiated.

Of all FBOs, 37% (28/75) were given a grade D for multiple inspected items and 87% (65/75) were given also a grade C for one or more items in 2014 (Table 2). Cases in which an enforcement process was initiated (n = 29) had significantly more often multiple non-compliances than cases in which an enforcement process was not initiated (Table 2). In addition, the FBO had been given a prior grade C in 2014 for the same inspected items significantly more commonly in cases in which an enforcement process was initiated than in cases in which an enforcement process was not initiated (Table 2).

Of the FBOs, 31% (23/75) had been inspected according to the Oiva evaluation system in the previous year in 2013. Of these FBOs, 91% (21/23) had already then been given a grade C or D for the same or other inspected items graded as D in 2014 (Table 2). No significant
differences in the compliance history of the FBOs in 2013 were observed between the cases grouped by initiating or not initiating an enforcement process (Fisher’s exact test $p = 0.596$) (Table 2).

Among all cases, the most commonly reported inspected items that were graded as D were related to temperature control and prevention of cross-contamination during preparation and storage (37%; 28/75 cases), to temperature control and prevention of cross-contamination during serving and selling (29%; 22/75) and to self-checking plan (29%; 22/75) (Figure 1). Non-compliances related to suitability and maintenance of the premises and to hygienic working practices and proficiency of the personnel were significantly more common among the cases in which an enforcement process was initiated than in the cases in which an enforcement process was not initiated (Fisher’s exact test $p = 0.004$ and $p = 0.025$, respectively) (Figure 1).

3.4 Correction of non-compliances and follow-up inspections

According to the interviews of officials, the FBOs corrected the non-compliance already during the inspection visit in 19% (14/75) of the cases. If not corrected during the inspection, the non-compliances were corrected by the end of 2015 at the latest in 64% (48/75) of the cases. In 12% (9/75) of the cases, the FBO changed or ceased operations. In 5% (4/75) of the cases, the non-compliances were not corrected by the end of 2015.

In cases where the non-compliances were corrected by the end of 2015, these non-compliances were corrected by the first follow-up inspection in 63% (30/48) of the cases. In the remaining cases, the number of follow-up inspections needed for correction of the non-compliances ranged from two to five.
3.5 Reasons for not using enforcement measures

The most commonly cited reason for not using enforcement measures was that the non-compliance was corrected during the given time limit or already during the inspection visit (Table 3). FBO-related reasons, such as change in ownership of the company, cessation of operations or the official’s perceptions of the FBO’s cooperative attitude and striving for compliance, were also mentioned as reasons for preferring negotiation instead of enforcement measures (Table 3). In 30% (14/46) of the cases in which an enforcement process was not initiated despite the grade D, more than one reason was given for not using enforcement measures.

When the officials were asked about their views on the common alignment in their unit regarding whether a grade D is used and an enforcement process is consequently initiated, the most common response (31%; 11/36 officials in 53%; 8/15 units) was that a grade C is first given one to three times, and if an FBO does not correct the non-compliance, a grade D is eventually given and an enforcement process initiated (Table 4). However, variation and discrepancies were observed in the responses within and between units. In many units, at least one official stated that the grade to be given and the use of enforcement measures are deliberated on a case-dependent basis or that their unit has no jointly agreed alignment on the subject. Moreover, in almost one-third of the units, at least one official stated that a grade D is avoided to refrain from the use of enforcement measures (Table 4). In addition, in 33% (5/15) of the units, the interviewed officials expressed contradictory views on whether or not their unit has a guideline for the use of enforcement measures. In one unit, however, the practices, guidance and routine in the use of enforcement measures appeared to be particularly clear, although deliberated on a case-dependent basis, and all interviewed officials (n = 3) highlighted the expertise of the head and the officials in employing these measures.
4. Discussion

Consistency in the evaluation of officials regarding the severity of violations and needed control actions is of great importance for uniformity of enforcement. Already before introduction of the Oiva evaluation system, regular education of inspecting officials and detailed guidelines have been provided. However, although the officials consider the guidelines as helpful in improving the consistency of using enforcement measures, adoption of national guidelines and unifying the practices of many individual control units are not simple processes, and the system has not yet fully succeeded in harmonising the control measures in practice. This is reflected in the variation and discrepancy found within and between units in the opinions of interviewed officials regarding the alignments of their unit in the use of a grade D and initiating the enforcement process as its consequence. Moreover, in one-third of the units, interviewed officials had differing awareness of the existence of guidelines for the use of enforcement measures in their own unit. This observed variation and lack of awareness is in line with the previously reported existence of tacit knowledge and defective adoption of operational procedures in local food control units (Lääkkö-Roto, Lundén, Heikkilä, & Nevas, 2016). Inconsistent enforcement practices between and within units may lead to FBOs of unequal standing and, in the worst case, compromise food safety. Therefore, further effort in the units should be directed towards unifying the enforcement practices by ensuring adequate orientation of the personnel and verifying that the established procedures are adopted in daily work. Moreover, as reported by Lääkkö-Roto and Nevas (2014), municipal officials find that cross-auditing between the units has potential for improving the consistency of controls. Learning from the good practices of units with a strong routine would be beneficial for other units; further research should focus on identifying such units and exploring their characteristics and practices.

Our findings on varying practices to use a grade D and enforcement measures may indicate differences in the interpretations of officials regarding the evaluation criteria, non-compliances, their risk for food safety and the control actions needed. In a study by Lääkkö-Roto et
al. (2015), over 50% of food control officials considered ‘evaluation of food hygiene and operational hygiene’ and ‘evaluation of the severity of neglecting legislative requirements and the needed control actions’ as the most relevant training areas to improve the quality and efficacy of official food control. Other previous studies have also reported that the judgements of inspectors are subjective and influenced by several factors (Johnson, Almanza, & Nelson, 2014) and their opinions vary regarding the most effective enforcement approach and required control measures for non-compliance (Läikkö-Roto et al., 2015; Mascini & Wijk, 2009). Moreover, differences among inspectors have been reported to have a significant impact on the probability of violation occurrence in the inspections and restaurant inspection scores (Lee, Nelson, & Almanza, 2012). According to a recent empirical study by Ho (2017), peer review within a food control authority appears to improve consistency of inspections by decreasing the variation among inspectors, and it could thus be beneficial to include peer review in the standard practices of food control organisations.

Despite the observed uncertainty and inconsistencies in the alignments in the units, the reasons for not using enforcement measures appear to be mainly justified and reasonable, as the most commonly mentioned reason by the officials was that the non-compliance was corrected during a specified time limit or already during the inspection. Moreover, discretion regarding the food safety risk caused by the non-compliance was also highlighted among the officials in deciding whether to initiate an enforcement process. Based on the inspection reports and the interviews of officials, the poorest grades and enforcement measures are used mostly in cases with recurrent or serious violations such as improper temperature control, inadequate prevention of cross-contamination or unhygienic working practices. These violations, considered critical for food safety and prevention of foodborne outbreaks (e.g. EFSA & ECDC, 2016; Gormley et al., 2011; Todd, Greig, Bartleson, & Michaels, 2007; U.S. Food and Drug Administration, 2013), are commonly detected during routine inspections of food premises (Guiducci, Copeland, Dorsey, & Edelstein, 2011; Phillips, Elledge, Basara, Lynch, & Boatright, 2006; Reske, Jenkins, Fernandez, VanAmber,
In cases in which an enforcement process was initiated, the FBO had
significantly more often multiple non-compliances or had been given a preceding request to correct
the non-compliance than in cases in which an enforcement was not initiated. These findings indicate
that officials have a risk-based approach to control and primarily attempt to get the FBO to comply
with the requirements first through requesting and guidance before using stricter and more coercive
measures. This is in line with the requirements stated in the EU regulation on official controls
stipulating that the authority shall take into account the nature of the non-compliance and the FBO’s
compliance history when deciding which action to take (EC No 882/2004). Similar findings on the
risk-based and progressive use of enforcement measures have also previously been reported
(Kettunen et al., 2015; Lundén, 2013).

Official- or unit-related reasons, such as reluctance to use enforcement measures or
unfamiliarity with the process, were mentioned by a few officials for not using enforcement
measures. As the administrative procedures are often perceived as lengthy and time-consuming
(Kettunen et al., 2017), officials are likely tempted to try to get the non-compliance corrected in the
simplest way, which is usually by request and stipulation of a short deadline in the inspection
report. This was also pointed out by some food control officials who perceived that a grade D,
which must be published for consumers to see, itself encourages correction of the non-compliance
more effectively than enforcement measures. However, one way to avoid the enforcement process
might be refraining from the use of a grade D. The ultimate aims of disclosure systems are to
increase the efficacy of enforcement by enhancing the incentives of FBOs to comply and to provide
consumers with accurate information to increase transparency (da Cunha et al., 2016; Djekic et al.,
2014; Evira, 2015; Ho, 2012). Thus, inconsistency in violation assessment and grading and a
narrow use of the grading scale may compromise the expediency of the disclosure (Ho, 2012).

Enforcement measures are an important control tool and sometimes the only way to
obtain compliance. In the majority of cases in which an enforcement process was initiated, the FBO
had been given a prior grade C or D and a request to correct the non-compliance, but these requests
had not induced compliance. Moreover, even the threat of enforcement measures may promote
compliance, as hearing about a prospective enforcement decision led to correction of non-
compliances in almost half of the enforcement cases. Hearing about future enforcement measures
probably helps some FBOs realise the significance of the violations, thus encouraging their
correction. However, not using enforcement measures in four out of nine cases in which the FBO
was given a grade D repeatedly due to same non-compliances clearly contradicts the guidelines and
indicates that enforcement measures are not always applied when needed. Furthermore, although
the recurrence of non-compliances is among the main reasons for initiating an enforcement process
according to the guidelines as well as based on the analysis of the inspection reports, the share of
FBOs with a history of non-compliances in 2013 did not differ among cases in which an
enforcement process was initiated or not. Although comparing the efficacy of different control
measures in correction of non-compliances would require a larger data set of cases and warrants
additional research, our results suggest that more rapid progress to stricter control measures and a
lower threshold for initiating an enforcement process after detection of significant or recurrent
violations could accelerate the correction of food safety violations and increase the efficacy and
risk-basis of control. A smooth initiation of an enforcement process requires appropriate practical
tools in the unit, such as guidelines for the process and templates for decisions, and adequate
expertise and confidence of the officials in the process (Kettunen et al., 2017).

The compliance of FBOs with the requests by the officials was somewhat weak, as
non-compliances were not corrected by the first follow-up inspection in almost 40% of the cases in
which the non-compliance was not corrected during the inspection visit. Moreover, the number of
follow-up inspections needed for correction of non-compliances was as high as five inspections in a
few cases. Furthermore, over 90% of the FBOs that had been inspected in 2013 had already at that
time the same or other non-compliances as those graded as D in 2014. The persistent non-
compliances indicate that certain FBOs lack food safety practices in their operations or have overall
recklessness regarding food safety requirements. Inadequate hygiene practices and lack of personnel
proficiency were especially common among the cases in which an enforcement process was
initiated, indicating that these FBOs have a poor attitude towards food hygiene. Several studies
report that FBOs may have false assumptions of the hygiene level of their company and may not
perceive the risks caused by the non-compliance in their operations to be significant (Baş, Ersun, &
Kıvanç 2006; Clayton, Griffith, Price, & Peters, 2002; Jianu & Chiş 2012; Walker, Pritchard, &
Forsythe, 2003). Some reasons for non-compliance may be related to the economic burden of
achieving and maintaining compliance. For example, non-compliances related to suitability and
maintenance of the premises are often expensive to correct or may require major operational
changes. Inadequate financial resources, together with a lack of knowledge, expertise,
understanding, time, motivation and trust in food safety legislation are among the reported
challenges for compliance of FBOs or for implementing food safety systems (Baş, Yüksel, &
Çavuşoğlu, 2007; Mensah & Julien, 2011; Yapp & Fairman, 2006). Recurrent non-compliance with
food safety standards poses a serious public health threat, as food premises with persistent or
multiple food safety violations are reported as likely locations of foodborne outbreaks (Kassa, 2001;
Petran et al., 2012a). Future research should focus on detecting other FBO-related factors that may
predict recklessness towards food safety requirements; this knowledge could help in rapidly
targeting an effective intervention in the operations of these FBOs.

In addition to the challenges regarding consistency and risk-basis in using
enforcement measures in local food control units, our study indicates some discrepancy in the
statistics reported from the units to the national database. Although the information on initiating an
enforcement process was not reported as a result of an inspection, interviews of officials and
analysis of the inspection reports revealed that an enforcement process was actually initiated in
more than one-third of these cases. This might indicate unclear or incongruous instructions for
recording control actions in the units. Since conducting this study, the reporting system for food control data has been developed and improved (Evira, 2017); this is important for effective utilization of the nationally collected data in assessing local food control performance and developing the efficacy of control actions. In addition, further research on the interpretation of and compliance with national-level inspection guidelines by the officials is anticipated to increase consistency of implementing the grading and disclosure system.

5. Conclusions

Our study indicates that although the national evaluation guidelines are seen as helpful in improving the consistency of using administrative enforcement measures, the control actions vary on a case-dependent basis and within and between local food control units. Officials also appear to be somewhat uninformed or uncertain of the joint alignments of their units. Administrative enforcement measures are mostly used in cases with multiple or repeated non-compliances and if milder control measures have proved inadequate, demonstrating a risk-based and gradual approach to enforcement. However, recurrent non-compliances indicate recklessness of some FBOs towards food safety requirements and deficiencies in the efficacy of enforcement. A lower threshold of using enforcement measures for FBOs with repeated violations appears to enhance the correction of violations, thus decreasing the likelihood of public health hazards. Establishment of clear procedures for enforcement, orientation of personnel and peer review within the local control units, in addition to cooperation, cross-auditing and discussion about the alignments between the units should be further enhanced to improve the consistency of implementing the evaluation and disclosure system and enforcement practices.

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Table 1. Oiva evaluation scale, definition of the grades and control measures to be taken by food control authorities according to Oiva evaluation guidelines (Evira, 2013, 2016b).

<table>
<thead>
<tr>
<th>Oiva grade</th>
<th>Definition of grade</th>
<th>Control measure to be taken by food control authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (Excellent)</td>
<td>Operations comply with food legislation requirements.</td>
<td>No control action needed.</td>
</tr>
<tr>
<td>B (Good)</td>
<td>There are small issues that do not impair food safety or mislead consumers.</td>
<td>Official notifies the issues in the inspection report.</td>
</tr>
<tr>
<td>C (To be corrected)</td>
<td>There are non-compliances that impair food safety or mislead consumers. Non-compliances must be corrected within a set time limit.</td>
<td>Food control authority should initiate an administrative enforcement process to ensure compliance. If justifiable, official can alternatively give the FBO a written request to correct the non-compliance within a time limit.</td>
</tr>
<tr>
<td>D (Poor)</td>
<td>There are non-compliances that jeopardise food safety or considerably mislead consumers. Non-compliances must be corrected immediately.</td>
<td>Food control authority must initiate an administrative enforcement process to ensure compliance.</td>
</tr>
<tr>
<td>Control history and overall compliance of FBOs</td>
<td>All cases % (n/N)</td>
<td>Cases in which an enforcement process was initiated % (n/N)</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-------------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>FBO was given a grade D for multiple inspected items in 2014</td>
<td>37 (28/75)</td>
<td>59 (17/29)</td>
</tr>
<tr>
<td>FBO was given a prior grade C in 2014 for the same inspected items that were eventually given a grade D</td>
<td>37 (28/75)</td>
<td>66 (19/29)</td>
</tr>
<tr>
<td>FBO was given a grade C in 2014 for other inspected item in addition to those that were given a grade D</td>
<td>87 (65/75)</td>
<td>79 (23/29)</td>
</tr>
<tr>
<td>FBO was given a grade C or D for the same or other inspected item already in 2013</td>
<td>91 (21/23) $^b$</td>
<td>90 (9/10) $^b$</td>
</tr>
</tbody>
</table>

$^a$ Comparisons are made between the cases based on initiating or not initiating an administrative enforcement process.

$^b$ N refers to the FBOs that were inspected in 2013.

$^*$ An asterisk indicates statistical significance in the differences between groups.
Table 3. Reasons for not using administrative enforcement measures in cases (N = 46) despite the given grade D according to food control officials' interviews.

<table>
<thead>
<tr>
<th>Reason for not initiating an enforcement process ¹</th>
<th>% of cases (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-compliance was corrected during set time limit</td>
<td>52 (24)</td>
</tr>
<tr>
<td>Non-compliance was corrected during the inspection</td>
<td>30 (14)</td>
</tr>
<tr>
<td>FBO changed or ceased operations</td>
<td>17 (8)</td>
</tr>
<tr>
<td>Other FBO-related reason ²</td>
<td>15 (7)</td>
</tr>
<tr>
<td>Non-compliance did not jeopardize food safety</td>
<td>13 (6)</td>
</tr>
<tr>
<td>Official- or unit-related reason ³</td>
<td>11 (5)</td>
</tr>
<tr>
<td>Other reason ⁴</td>
<td>2 (1)</td>
</tr>
</tbody>
</table>

¹ There may be more than one reason per case for not initiating an enforcement process.
² FBO was part of a chain that takes care of correction of non-compliance, FBO is not responsible of the maintenance of the premises or language barrier between FBO and food control official.
³ Reluctance to use enforcement measures in the unit, preference to negotiate with the FBO instead of using enforcement measures, using enforcement measures is difficult or time-consuming, the official is not familiar with the process, the FBO is striving for compliance, or using enforcement impairs the cooperation between the FBO and official.
⁴ The case is still pending and the use of enforcement measures is partly under the jurisdiction of Finnish Food Safety Evira.
Table 4. Opinions of interviewed officials (n = 42) on whether a grade D is used and an administrative enforcement process initiated as its consequence in their unit (n = 15).

<table>
<thead>
<tr>
<th>Unit</th>
<th>n of interviewed officials</th>
<th>Opinions of interviewed officials a</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7</td>
<td>B, C, C, E, E, F, G, G</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>A, A, C, C, E, E, H</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>B, D, D, D, F, F</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>A, B, E, H</td>
</tr>
<tr>
<td>5</td>
<td>3</td>
<td>A, B, B, F, H, H, H</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>C, D, F, G, G</td>
</tr>
<tr>
<td>7</td>
<td>4</td>
<td>D, D, D, F, G, G, G</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
<td>B, F</td>
</tr>
<tr>
<td>9</td>
<td>2</td>
<td>D, D, E, E</td>
</tr>
<tr>
<td>10</td>
<td>4</td>
<td>A, A, A, C, E</td>
</tr>
<tr>
<td>11</td>
<td>3</td>
<td>A, E, F, G</td>
</tr>
<tr>
<td>12</td>
<td>3</td>
<td>E</td>
</tr>
<tr>
<td>13</td>
<td>2</td>
<td>E</td>
</tr>
<tr>
<td>14</td>
<td>1</td>
<td>A, H</td>
</tr>
<tr>
<td>15</td>
<td>1</td>
<td>G</td>
</tr>
</tbody>
</table>

a One letter indicates one opinion of an official. One official may have given many opinions and thus the number of opinions may be higher than the number of interviewed official per unit.

Definitions of the letters describing the opinions of officials:
A = An enforcement process is initiated always if a grade D is given.
B = An enforcement process is initiated if a grade D is given twice.
C = An enforcement process is initiated if the non-compliance jeopardizes food safety.
D = A grade D can be used irrespective of whether an enforcement process is to be initiated or not.
E = First a grade C is given one to three times and if an FBO does not correct the non-compliance, a grade D is eventually given and an enforcement process is initiated.
F = The grade to be given and the initiation of an enforcement process are deliberated on a case-dependent basis.
G = No jointly agreed alignment on using the grade D or initiating an enforcement process.
H = Grade D is avoided in order to refrain from the use of enforcement measures.
Figure 1.

The diagram illustrates the frequency of different aspects inspected in food establishments, categorized into those in which an administrative enforcement process was initiated (n = 29) and those in which no such process was initiated (n = 46). The categories include:

- Temperature control and prevention of cross-contamination during preparation and storage
- Temperature control and prevention of cross-contamination during selling and serving
- Self-checking plan
- Suitability and maintenance of the premises and equipment
- Hygienic working practices and proficiency of the personnel
- Information given on food (labelling and marketing)
- Cleanliness of premises, surfaces and equipment
- Traceability of food
- Prevention of cross-contamination of substances causing allergies and intolerances
- Handling of animal by-products
- In-house control sampling of foodstuff
- Food contact and packaging materials
Figure 1. Occurrence of different types of inspected items that were given a grade D in the Oiva inspection reports in 2014 in all cases and in cases in which an administrative enforcement process was initiated or not.

* An asterisk indicates a significant difference in the occurrence of non-compliances related to the item between the cases in which an enforcement process was initiated and the cases in which no enforcement process was initiated (Fisher’s exact test p < 0.05).