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Kettunen, Karoliina

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

Karoliina Kettunen[1], Susanna Pesonen[2], Janne Lundén[1] and Mari Nevas[1]

[1] Department of Food Hygiene and Environmental Health, Faculty of Veterinary Medicine, P.O. Box 66, 00014 University of Helsinki, Finland

[2] Regional State Administrative Agency for Southwestern Finland, P.O. Box 22, 20801 Turku, Finland

Corresponding author: Karoliina Kettunen, Department of Food Hygiene and Environmental Health, Faculty of Veterinary Medicine, P.O. Box 66, 00014 University of Helsinki, Finland

E-mail: karoliina.r.kettunen@helsinki.fi

22 **Abstract**

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

45

46 **Keywords**

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

49

## 50 1. Introduction

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

65 A responsive enforcement approach, in which the enforcement actions are adjusted to
66 the control history and behaviour of the business, is considered to be the most effective approach to
67 promote compliance among regulated business (Ayres & Braithwaite, 1992; OECD, 2014; Yapp &
68 Fairman, 2006). However, despite the recognised benefits of a responsive approach, inconsistency
69 in enforcement practices is a problem (Ayres & Braithwaite, 1992; Mascini & Wijk, 2009). Also in
70 the field of official food safety control, inconsistency is a widely reported issue (e.g., Hutter &

71 Amodu, 2009; Ho, 2012; Lee-Woolf, Bain, & Fell, 2015; Läikkö-Roto, Mäkelä, Lundén, Heikkilä,
72 & Nevas, 2015; Pham, Jones, Sargeant, Marshall, & Dewey, 2010). Underlying reasons for
73 inconsistent enforcement practices and inspection procedures in official food control have been
74 discussed to be e.g. ambiguity in legislative requirements, various factors related to characteristics
75 of control authority and the nature of the relationship between the official and the FBO (Hutter &
76 Amodu, 2009; Läikkö-Roto et al., 2015; Mascini & Wijk, 2009).

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

84 Consistency of controls is a prerequisite for publishing inspection results (Griffith,
85 2005). Inspections of Finnish food premises have been conducted via a disclosure system, known as
86 the Oiva evaluation system, since May 2013 in the food retail sector and since May 2015 in the
87 food industry overall. The inspection results are expressed via smiley faces that range from an Oiva
88 grade A ('excellent'), B ('good'), C ('to be corrected') to D ('poor') (Evira, 2013) (Table 1). In the
89 retail sector, the inspection report must be provided at the entrance of the food premises or in
90 another place easily accessible to customers as well as on the company internet pages (Evira,
91 2016a). The inspections are conducted using standardised, publicly available Oiva evaluation
92 guidelines. The guidelines define the Oiva grade to be given to each inspected item and the control
93 actions that the food control officials should take based on the severity and recurrence of the
94 observed food safety violation (Evira, 2013). According to the guidelines, food control authorities
95 should always initiate an administrative enforcement process (henceforth 'enforcement process') if

96 food safety is jeopardised or the consumer is considerably misled (grade D) (Table 1). An
97 enforcement process should also be initiated if the non-compliance impairs food safety or misleads
98 the consumer (grade C) and if other control measures are inadequate, or if the non-compliance is
99 recurrent (Table 1).

100 Administrative enforcement measures (henceforth 'enforcement measures') available
101 to Finnish food control authorities include such measures as giving an order to correct the non-
102 compliance, prohibition of placing a food on the market, ordering a withdrawal of food from the
103 market or restriction or suspension of operations (Food Act, 2011). The use of enforcement
104 measures has been reported to be an important tool to ensure that FBOs correct severe or recurrent
105 food safety violations (Kettunen et al., 2015). However, the lengthy and time-consuming
106 administrative procedures decrease the efficacy and applicability of the measures (Kettunen et al.,
107 2015, 2017). Moreover, officials' uncertainty, shortcomings in their knowledge of administrative
108 procedures and lack of routine have been reported to hinder the use of enforcement measures
109 (Kettunen et al., 2017; Lepistö & Hänninen, 2011; Lepistö, Nevas, & Hänninen, 2009).

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

114

115 **2. Material and methods**

116 2.1 Questionnaire

117 As a part of a questionnaire developed for a larger survey regarding the use of enforcement
118 measures and related challenges (Kettunen et al., 2017), we investigated the opinions of local food
119 control officials about the influence of the Oiva evaluation system on the use of enforcement

120 measures and its consistency within and between units. The electronic questionnaire was issued to
121 the inspecting food control officials of all 62 Finnish local food control units as well as to the heads
122 of these units in September 2015. The part of the questionnaire regarding the influence of the Oiva
123 system on the use of enforcement measures included the following three claims: 1) The Oiva
124 evaluation guidelines provide unambiguous criteria for using enforcement measures; 2) The Oiva
125 evaluation guidelines provide better prerequisites for consistent use of enforcement measures within
126 our control unit; 3) The Oiva evaluation guidelines provide better prerequisites for consistent use of
127 enforcement measures between control units. These claims appeared on a four-point Likert scale (1
128 = fully disagree, 2 = partly disagree, 3 = partly agree, 4 = fully agree). The respondents were also
129 asked if enforcement measures had been used in their unit in the last three years. Respondents of the
130 units in which enforcement measures had been used were asked whether the Oiva system has had an
131 effect on the threshold of using enforcement measures in their unit according to the following scale:
132 the threshold has clearly lowered, has somewhat lowered, is the same as before the Oiva evaluation
133 system, has somewhat risen or has clearly risen. In addition, respondents could elaborate on their
134 answers to closed questions in the subsequent open-ended questions 'Please clarify your answer if
135 needed'.

136

137 2.2 Inspection reports

138 Within the areas of the 45 Finnish local food control units that responded to the electronic survey
139 described above, we searched the national database of food control data to detect the food retail
140 premises that had been given a grade D during an Oiva inspection in 2014, but in which no
141 enforcement measures had been used based on reported data. The number of such food premises
142 was 75, located in the areas of 15 units. Of these premises, 71% (53/75) were restaurants, including
143 cafeterias and other food serving premises, and 29% (22/75) were retail stores. For these premises,
144 we collected inspection reports of Oiva inspections from the introduction of the Oiva evaluation

145 system in May 2013 until December 2015 from the database. The inspected items that were graded
146 as D in the Oiva inspection reports were categorised according to the 17 main categories of
147 inspected items presented in the Oiva evaluation guidelines for notified food premises (Evira,
148 2016b).

149

150 2.3 Interviewing food control officials

151 An interview form was developed for the local food control officials (henceforth 'officials') who
152 had conducted Oiva inspections of the 75 FBOs described above in 2014. The interviews were
153 conducted by one author (SP) of the study via telephone between December 2015 and March 2016.
154 The aim of the interview was to explore the factors related to the official, control unit and control
155 history of the FBO that would have influenced the use of enforcement measures in those cases in
156 2014. In five cases, the official who had conducted the control actions was not available for
157 interview; in these cases a colleague or superior of the official was interviewed.

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

164

165 2.3 Data analysis

166 All data were processed using SPSS statistical software (IBM SPPS Statistics 22.0, NY, USA). In
167 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 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 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

181 **3. Results**

182 3.1 Received responses, analysed inspection reports and conducted interviews

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 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.

191 The number of interviewed officials was 42, ranging from one to seven interviewees
192 per unit. Of the interviewed officials, 43% (18/42) had conducted inspections in more than one food
193 premises included in the study.

194

195 3.2 Influence of the Oiva evaluation system on the use of enforcement measures

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

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

214 enhanced the correction of non-compliances, thus decreasing the need for using enforcement
215 measures.

216

217 3.3 Initiation of an enforcement process and non-compliances of FBOs

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

228 Of all FBOs, 37% (28/75) were given a grade D for multiple inspected items and 87%
229 (65/75) were given also a grade C for one or more items in 2014 (Table 2). Cases in which an
230 enforcement process was initiated (n = 29) had significantly more often multiple non-compliances
231 than cases in which an enforcement process was not initiated (Table 2). In addition, the FBO had
232 been given a prior grade C in 2014 for the same inspected items significantly more commonly in
233 cases in which an enforcement process was initiated than in cases in which an enforcement process
234 was not initiated (Table 2).

235 Of the FBOs, 31% (23/75) had been inspected according to the Oiva evaluation
236 system in the previous year in 2013. Of these FBOs, 91% (21/23) had already then been given a
237 grade C or D for the same or other inspected items graded as D in 2014 (Table 2). No significant

238 differences in the compliance history of the FBOs in 2013 were observed between the cases
239 grouped by initiating or not initiating an enforcement process (Fisher's exact test $p = 0.596$) (Table
240 2).

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

249

250 3.4 Correction of non-compliances and follow-up inspections

251 According to the interviews of officials, the FBOs corrected the non-compliance already during the
252 inspection visit in 19% (14/75) of the cases. If not corrected during the inspection, the non-
253 compliances were corrected by the end of 2015 at the latest in 64% (48/75) of the cases. In 12%
254 (9/75) of the cases, the FBO changed or ceased operations. In 5% (4/75) of the cases, the non-
255 compliances were not corrected by the end of 2015.

256 In cases where the non-compliances were corrected by the end of 2015, these non-
257 compliances were corrected by the first follow-up inspection in 63% (30/48) of the cases. In the
258 remaining cases, the number of follow-up inspections needed for correction of the non-compliances
259 ranged from two to five.

260

### 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 (Läikkö-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 Läikkö-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 Läikkö-Roto et

310 al. (2015), over 50% of food control officials considered 'evaluation of food hygiene and
311 operational hygiene' and 'evaluation of the severity of neglecting legislative requirements and the
312 needed control actions' as the most relevant training areas to improve the quality and efficacy of
313 official food control. Other previous studies have also reported that the judgements of inspectors are
314 subjective and influenced by several factors (Johnson, Almanza, & Nelson, 2014) and their opinions
315 vary regarding the most effective enforcement approach and required control measures for non-
316 compliance (Läikkö-Roto et al., 2015; Mascini & Wijk, 2009). Moreover, differences among
317 inspectors have been reported to have a significant impact on the probability of violation occurrence
318 in the inspections and restaurant inspection scores (Lee, Nelson, & Almanza, 2012). According to a
319 recent empirical study by Ho (2017), peer review within a food control authority appears to improve
320 consistency of inspections by decreasing the variation among inspectors, and it could thus be
321 beneficial to include peer review in the standard practices of food control organisations.

322 Despite the observed uncertainty and inconsistencies in the alignments in the units, the
323 reasons for not using enforcement measures appear to be mainly justified and reasonable, as the
324 most commonly mentioned reason by the officials was that the non-compliance was corrected
325 during a specified time limit or already during the inspection. Moreover, discretion regarding the
326 food safety risk caused by the non-compliance was also highlighted among the officials in deciding
327 whether to initiate an enforcement process. Based on the inspection reports and the interviews of
328 officials, the poorest grades and enforcement measures are used mostly in cases with recurrent or
329 serious violations such as improper temperature control, inadequate prevention of cross-
330 contamination or unhygienic working practices. These violations, considered critical for food safety
331 and prevention of foodborne outbreaks (e.g. EFSA & ECDC, 2016; Gormley et al., 2011; Todd,
332 Greig, Bartleson, & Michaels, 2007; U.S. Food and Drug Administration, 2013), are commonly
333 detected during routine inspections of food premises (Guiducci, Copeland, Dorsey, & Edelstein,
334 2011; Phillips, Elledge, Basara, Lynch, & Boatright, 2006; Reske, Jenkins, Fernandez, VanAmber,

335 & Hedberg, 2007). In cases in which an enforcement process was initiated, the FBO had
336 significantly more often multiple non-compliances or had been given a preceding request to correct
337 the non-compliance than in cases in which an enforcement was not initiated. These findings indicate
338 that officials have a risk-based approach to control and primarily attempt to get the FBO to comply
339 with the requirements first through requesting and guidance before using stricter and more coercive
340 measures. This is in line with the requirements stated in the EU regulation on official controls
341 stipulating that the authority shall take into account the nature of the non-compliance and the FBO's
342 compliance history when deciding which action to take (EC No 882/2004). Similar findings on the
343 risk-based and progressive use of enforcement measures have also previously been reported
344 (Kettunen et al., 2015; Lundén, 2013).

345 Official- or unit-related reasons, such as reluctance to use enforcement measures or
346 unfamiliarity with the process, were mentioned by a few officials for not using enforcement
347 measures. As the administrative procedures are often perceived as lengthy and time-consuming
348 (Kettunen et al., 2017), officials are likely tempted to try to get the non-compliance corrected in the
349 simplest way, which is usually by request and stipulation of a short deadline in the inspection
350 report. This was also pointed out by some food control officials who perceived that a grade D,
351 which must be published for consumers to see, itself encourages correction of the non-compliance
352 more effectively than enforcement measures. However, one way to avoid the enforcement process
353 might be refraining from the use of a grade D. The ultimate aims of disclosure systems are to
354 increase the efficacy of enforcement by enhancing the incentives of FBOs to comply and to provide
355 consumers with accurate information to increase transparency (da Cunha et al., 2016; Djekic et al.,
356 2014; Evira, 2015; Ho, 2012). Thus, inconsistency in violation assessment and grading and a
357 narrow use of the grading scale may compromise the expediency of the disclosure (Ho, 2012).

358 Enforcement measures are an important control tool and sometimes the only way to
359 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-

385 compliances indicate that certain FBOs lack food safety practices in their operations or have overall
386 recklessness regarding food safety requirements. Inadequate hygiene practices and lack of personnel
387 proficiency were especially common among the cases in which an enforcement process was
388 initiated, indicating that these FBOs have a poor attitude towards food hygiene. Several studies
389 report that FBOs may have false assumptions of the hygiene level of their company and may not
390 perceive the risks caused by the non-compliance in their operations to be significant (Baş, Ersun, &
391 Kıvanç 2006; Clayton, Griffith, Price, & Peters, 2002; Jianu & Chiş 2012; Walker, Pritchard, &
392 Forsythe, 2003). Some reasons for non-compliance may be related to the economic burden of
393 achieving and maintaining compliance. For example, non-compliances related to suitability and
394 maintenance of the premises are often expensive to correct or may require major operational
395 changes. Inadequate financial resources, together with a lack of knowledge, expertise,
396 understanding, time, motivation and trust in food safety legislation are among the reported
397 challenges for compliance of FBOs or for implementing food safety systems (Baş, Yüksel, &
398 Çavuşoğlu, 2007; Mensah & Julien, 2011; Yapp & Fairman, 2006). Recurrent non-compliance with
399 food safety standards poses a serious public health threat, as food premises with persistent or
400 multiple food safety violations are reported as likely locations of foodborne outbreaks (Kassa, 2001;
401 Petran et al., 2012a). Future research should focus on detecting other FBO-related factors that may
402 predict recklessness towards food safety requirements; this knowledge could help in rapidly
403 targeting an effective intervention in the operations of these FBOs.

404 In addition to the challenges regarding consistency and risk-basis in using
405 enforcement measures in local food control units, our study indicates some discrepancy in the
406 statistics reported from the units to the national database. Although the information on initiating an
407 enforcement process was not reported as a result of an inspection, interviews of officials and
408 analysis of the inspection reports revealed that an enforcement process was actually initiated in
409 more than one-third of these cases. This might indicate unclear or incongruous instructions for

410 recording control actions in the units. Since conducting this study, the reporting system for food
411 control data has been developed and improved (Evira, 2017); this is important for effective
412 utilization of the nationally collected data in assessing local food control performance and
413 developing the efficacy of control actions. In addition, further research on the interpretation of and
414 compliance with national-level inspection guidelines by the officials is anticipated to increase
415 consistency of implementing the grading and disclosure system.

416

417 **5. Conclusions**

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

432

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436

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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).

| Oiva grade | Definition of grade | Control measure to be taken by food control authority |
|---|---|---|
| A (Excellent) | Operations comply with food legislation requirements. | No control action needed. |
| B (Good) | There are small issues that do not impair food safety or mislead consumers. | Official notifies the issues in the inspection report. |
| C (To be corrected) | There are non-compliances that impair food safety or mislead consumers. Non-compliances must be corrected within a set time limit. | 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. |
| D (Poor) | There are non-compliances that jeopardise food safety or considerably mislead consumers. Non-compliances must be corrected immediately. | Food control authority must initiate an administrative enforcement process to ensure compliance. |

**Table 2**

Table 2. Overall compliance and control history of FBOs based on whether an enforcement process was initiated or not.

| Control history and overall compliance of FBOs | All cases % (n/N) | Cases in which an enforcement process was initiated % (n/N) | Cases in which no enforcement process was initiated % (n/N) | Significance of differences between groups [a] |
|---|---|---|---|---|
| FBO was given a grade D for multiple inspected items in 2014 | 37 (28/75) | 59 (17/29) | 24 (11/46) | Fisher's exact test $p = 0.003$ * |
| FBO was given a prior grade C in 2014 for the same inspected items that were eventually given a grade D | 37 (28/75) | 66 (19/29) | 20 (9/46) | Fisher's exact test $p < 0.001$ * |
| FBO was given a grade C in 2014 for other inspected item in addition to those that were given a grade D | 87 (65/75) | 79 (23/29) | 91 (42/46) | Fisher's exact test $p = 0.171$ |
| FBO was given a grade C or D for the same or other inspected item already in 2013 | 91 (21/23) [b] | 90 (9/10) [b] | 92 (12/13) [b] | Fisher's exact test $p = 0.596$ |

[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**

Table 3. Reasons for not using administrative enforcement measures in cases (N = 46) despite the given grade D according to food control officials' interviews.

| Reason for not initiating an enforcement process [a] | % of cases (n) |
|---|---|
| Non-compliance was corrected during set time limit | 52 (24) |
| Non-compliance was corrected during the inspection | 30 (14) |
| FBO changed or ceased operations | 17 (8) |
| Other FBO-related reason [b] | 15 (7) |
| Non-compliance did not jeopardize food safety | 13 (6) |
| Official- or unit-related reason [c] | 11 (5) |
| Other reason [d] | 2 (1) |

[a] There may be more than one reason per case for not initiating an enforcement process.
[b] 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.
[c] 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.
[d] The case is still pending and the use of enforcement measures is partly under the jurisdiction of Finnish Food Safety Evira.

**Table 4**

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).

| Unit | n of interviewed officials | Opinions of interviewed officials [a] |
|---|---|---|
| 1 | 7 | B, C, C, E, E, F, G, G |
| 2 | 4 | A, A, C, C, E, E, H |
| 3 | 3 | B, D, D, D, F, F |
| 4 | 1 | A, B, E, H |
| 5 | 3 | A, B, B, F, H, H, H |
| 6 | 3 | C, D, F, G, G |
| 7 | 4 | D, D, D, F, G, G, G |
| 8 | 1 | B, F |
| 9 | 2 | D, D, E, E |
| 10 | 4 | A, A, A, C, E |
| 11 | 3 | A, E, F, G |
| 12 | 3 | E |
| 13 | 2 | E |
| 14 | 1 | A, H |
| 15 | 1 | G |

[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**

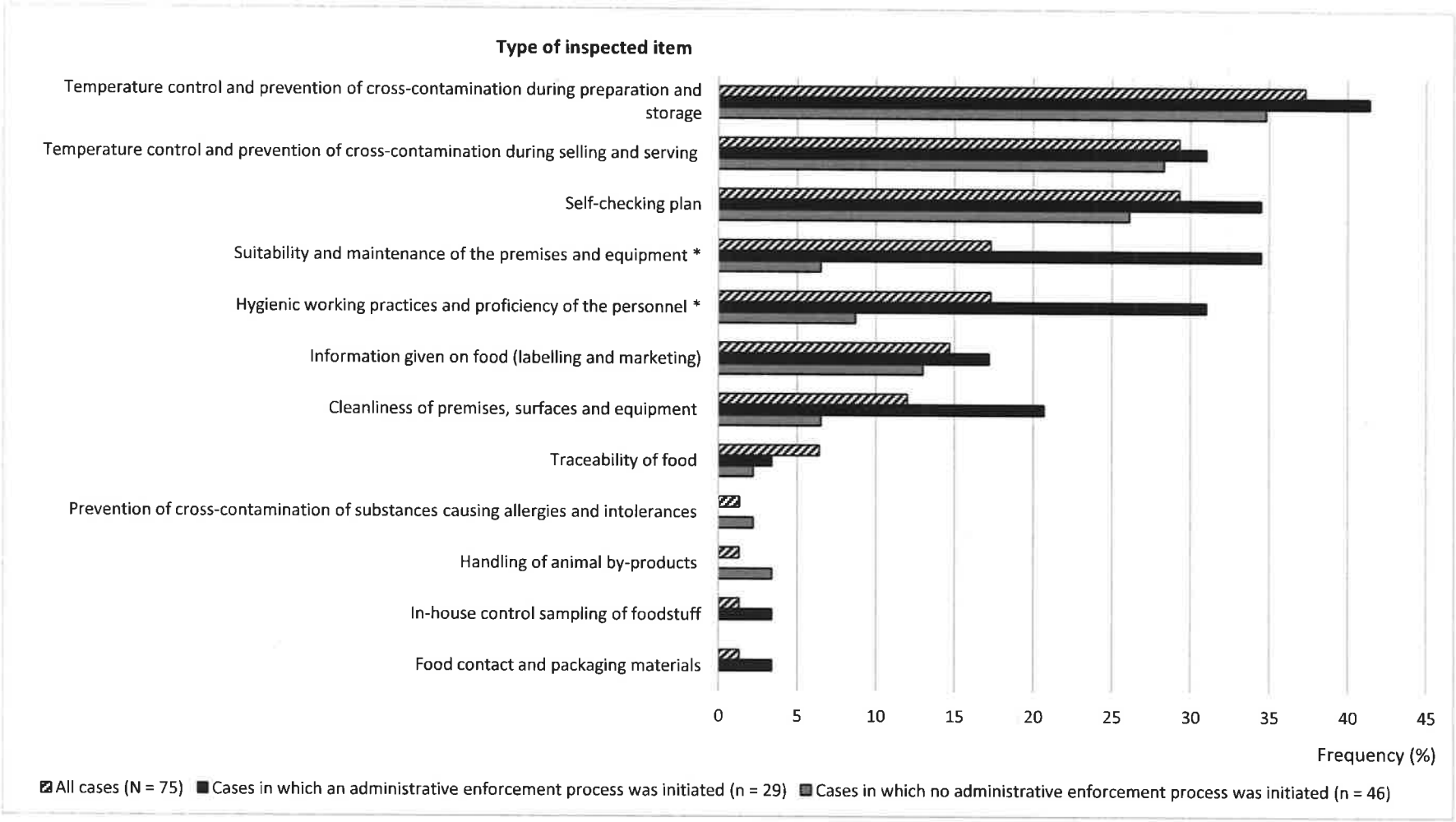


Figure 1.

**Figure caption**

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 $p < 0.05$).