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Differences between official inspections and third party audits of food establishments

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Abstract

Official food control inspections (official inspections) of food establishments and third party audits of food safety management systems (FSMSs) based on international standards both focus on food safety, which has raised discussions on whether FSMSs and their audits could reduce official inspections in food establishments. The aim of this study was to investigate whether the findings of official inspections and third party audits in food establishments are in alignment and to survey the inspectors' and food business operators' (FBOs) perceptions of official inspections and audits. The results can be used in planning the use of audit results as part of official food control. The results show that both inspectors and auditors recognized non-compliances/non-conformities, but significant discrepancies between the findings of official inspections and audits existed, making the utilization of audit results challenging. However, most of the FBOs and inspectors agreed that official inspections and audits overlap, and the majority also agreed that audits of a certified FSMS could under certain circumstances reduce official inspections.

Keywords: food safety; official control; official inspection; audit; food safety management system

1. Introduction

Food business operators (FBOs) are responsible for food safety in their establishment (EC, 2002) and are obligated to comply with the general hygiene requirements and Hazard Analysis and Critical Control Point (HACCP) principles stipulated in European Union (EU) regulations (EC, 2004a). FBOs implement self-checking programmes, for example, for sanitation, pest control, traceability and HACCP to fulfil these requirements. The premises and operations, including the self-checking programmes, are regularly inspected by the official food control (food control). In addition to the implementation of the requirements for food safety legislation, many FBOs implement food safety management systems (FSMSs) based on commercial international food safety standards (Lee, 2006; Trienekens & Zuurbier, 2008) such as those of the British Retail Consortium (BRC), the International Organization for Standardizations (ISO 22000) and the Food Safety System Certification (FSSC) 22000 (Mensah & Julien, 2011; Qijun & Batt, 2016) for food safety reasons and customers' requirements (Crandall, van Loo, O'Bryan, Mauromoustakos, Yiannas, Dyenson, & Berdnik, 2012; Fulponi, 2006). These standard-based FSMSs are audited by third party auditing bodies, which issue a certificate to the food business upon compliance with the standard (BRC, 2017; FSSC, 2016). Both food safety legislation and standards focus on food safety, and the implementation generates costs for FBOs (EC, 2004a,b; Trienekens & Zuurbier, 2008). This has raised discussions on the overlapping of official inspections and audits and on whether third party audits of FSMS could have a role in food control (Anonymous, 2013; CFIA, 2016; Martinez, Verbrugge, & Fearne, 2013; Räsänen & Vastamäki, 2016; Verbruggen & Havinga, 2015; Wright, Palmer, Shahriyer, Williams, & Smith, 2013).

EU legislation states that the food control should take into account the results of quality assurance programmes (EC, 2004b), and some countries have included the possibility to utilize FSMS and the audits of those in food control (Räsänen & Vastamäki, 2016). In EU

countries such as Belgium, Denmark, the UK and the Netherlands, the frequency of the official inspections can be reduced according to certain preconditions in food businesses with a certified FSMS (Räsänen & Vastamäki, 2016). In addition, Canada has declared a policy statement including this possibility (CFIA, 2016), and the US has contemplated a role for third party audits (FDA, 2017), showing that there is a wide interest in taking FSMSs into account in food control. Studies, however, on the comparability of official inspection and audit results have not been published according to the knowledge of the authors.

The utilization of FSMSs and their results in food control has raised concerns due to differences in the practices between food control and third party audits (Martinez et al., 2013; Wright et al. 2013; Räsänen and Vastamäki, 2016). Audits are carried out at least annually (FSSC, 2016; GFSI, 2011), and the FBO is usually aware of the audit well in advance, but most of the official inspections must be carried out unannounced. Furthermore, food control is risk based, which means that the risks involved with food operations influence the frequency of the official inspections (EC, 2004b; Evira, 2017). A major difference is that food control is independent from the food businesses, with the primary aim of safeguarding consumers (EC, 2004b), whereas the certification bodies are part of the market economy (Martinez et al., 2013). Economic interest involved with private standards may cause risks (Martinez et al., 2013) and, for example, has led to speculation on whether non-compliances could go unnoticed (Verbruggen & Havinga, 2015). In slaughterhouses in the Netherlands meat safety was considered to have decreased as a consequence of increasing the responsibility of the FBOs, but decreasing official control (Anonymous, 2014). Because the use of FSMSs and audits of those in food control raises such questions, it is important to investigate the comparability of official inspection and audit results.

The aim of our study is to investigate whether the findings of official inspections and third

party audits in food premises are in alignment with the special focus on non-compliances observed in official inspections and non-conformities in audits. Furthermore, we will investigate the perceptions of FBOs and local food control inspectors (inspectors) of official inspections and audits. The results can be used in developing the utilization of audits of FSMSs in food control.

2. Material and methods

2.1. Official inspection and audit reports

Food establishments that were members of the Finnish Food and Drink Industries' Federation were asked to participate in the study. Only food establishments that could provide both official inspection and audit reports from a one- to two-year period were included. Ten food establishments provided the data required (Table 1). The data comprised 66 official inspection and 18 audit reports. The official inspections and audits were conducted between the years 2013 and 2015. Among the 10 establishments, the certified FSMS based on ISO 22000 was the most frequent (Table 1). The official inspections were performed by different inspectors in different local food control units. The audits were performed by four international audit organisations and seven different auditors.

The inspected and audited issues were divided into 21 categories (Fig. 1). Observed non-compliance or non-conformity and possible time-limits for correction of those were detected from the official inspection and audit reports. The depth of the official inspection or the audit was not assessed because the official inspection and audit reports did not consequently describe how the official inspections or audits were performed, how thoroughly an area was covered and what kind of inspection and audit techniques were used. This study did not compare whether the legislation and the standards contained the same requirements, but focused on comparing official inspections and audits based on the reports.

2.2. Questionnaire for inspectors and FBOs

Local food control inspectors' and FBOs' views on food safety legislation and standards and official inspections and audits were inquired in spring 2015 with an electronic questionnaire (E-lomake, Eduix Oy). The questionnaire was sent to all local food control units in Finland (62 units) and to the members of the Finnish Food and Drink Industries' Federation (260 companies). The name of the local food control unit was not enquired to ensure the confidentiality of the responding inspectors. Therefore, the response rate was not possible to calculate. The FBOs were instructed to provide answers from only one person per food business. The FBOs were asked about the production type, the number of personnel (<10, 10-49, 50-249, ≥ 250) to describe the size of the establishment, and the existence of a certified FSMS at the food establishment. Sections for both respondent groups included the respondents' knowledge and perceptions of legislation and standards and views on the overlapping of official inspections and audits. The FBOs were further asked about the expertise of the inspectors and auditors and the impact of the official inspections and audits. The questionnaire consisted of multiple-choice questions and open-ended questions. The multiple-choice questions followed a four-step Likert scale (totally disagree, somewhat disagree, somewhat agree, totally agree). The impact of the official inspections and audits on food safety risk management was measured on a four-step scale (not at all, somewhat, clearly, very clearly). One reminder was sent.

2.3. Statistical analysis

We employed SPSS 22.0 (IBM, USA) software for a quantitative statistical analysis. The difference in the occurrence of non-compliances and non-conformities was tested with the Fisher exact test, which is applied in dichotomous values. The significance of the differences between the answers of the inspectors and FBOs were tested with the Mann-Whitney test (suitable for testing the difference between two groups), and the significance of the number of

personnel with the Kruskal-Wallis test (suitable for testing the difference between several groups). Both tests are nonparametric and can be used for small sample sizes. The differences in the opinions of the FBOs representing establishments handling food of animal origin or other establishments was also tested with Mann-Whitney test. The Wilcoxon Signed ranks test, which is used to testing the distribution of dependent samples, was applied for the FBOs' assessment of the inspections and audits. The statistical significance was considered at 95% confidence intervals ($p < 0.05$).

3. Results

3.1. Non-compliances/non-conformities observed in official inspections and audits

The frequency of non-compliances/non-conformities varied greatly between the official inspections and audits according to the reports (Fig. 1). The official inspection reports contained significantly more remarks on non-compliance concerning cross-contamination, maintenance, hygienic working methods, sanitation and sampling than the audit reports on non-conformities ($p < 0.05$), (Fig. 1). In some categories, such as HACCP and recall, the frequency of non-conformities was higher in the audits than of non-compliances in official inspections, although the difference was not statistically significant (Fig. 1).

Time limits for the correction of non-conformities was set on every non-conformity observed at the audits, according to the reports. The frequency of setting time limits for non-compliances observed in official inspections varied greatly. Most frequently a time limit was set for the correction of non-compliances concerning by-products (50%), waste management (33%), maintenance (26%), sanitation (25%) and separation of hygiene areas (25%). No time limits were set for non-compliances such as hygienic working methods or temperature control according to the reports.

3.2. Respondents of the questionnaire and their knowledge of food safety legislation and standards

The number of responding inspectors from local food control units was 28 and of the 260 members of Finnish Food and Drink Industries' Federation, 42 (response rate 16%). Among these FBOs 74% (31/42) had a certified FSMS (Table 2). One of the FBO's FSMS was based on BRC, while 28 FBOs that specified their FSMS relied on ISO 22000 and 19 FBOs on FSSC 22000. Both FBOs handling products of animal origin and other food establishments were represented among the respondents (Table 2). The size of the food establishments according to the number of personnel was as follows: 50-249 (55%), 10-49 (21%), > 250 (19%) and < 10 persons (5%).

All but one FBO (97%, 37/38) and half of the inspectors (50%, 14/28) reported to have at least some knowledge of a food safety standard. The most commonly known standard among FBOs and inspectors was ISO 22000 (90% and 29% were familiar with the standard respectively). However, most of the inspectors (86%) stated that they need more information about food safety standards, and 33% reported that they need more information concerning food safety legislation. Among the FBOs, 46% needed more information on food safety legislation and its implementation (Table 3). There were no significant differences in the answers of the FBOs according to the size of the food business.

3.3. Overlapping of food safety legislation and standards

The majority of inspectors and FBOs evaluated that food safety is sufficiently included in food safety legislation (96% and 98% respectively) and in the official inspections (100% and 95% respectively) (Table 3). The majority of inspectors and FBOs assessed that standards and audits include food safety sufficiently; however, significantly fewer inspectors than FBOs were of this opinion ($p < 0.001$) (Table 3). All of the inspectors and the majority of the FBOs

(90%) totally or partly agreed that food safety legislation and standards overlap, and the majority of the respondents assessed that the inspectors inspect and the auditors audit same issues (Table 3). No significant differences were observed in the answers between establishments of different sizes or the existence of a certified FSMS or not.

The FBOs and especially the inspectors stated that inconsistencies exist in the demands of the inspectors and auditors ($p < 0.001$) (Table 3). Interestingly, the analysis showed that the FBOs with a certified FSMS reported significantly fewer inconsistencies (21%, 6/28) than the FBOs with no certified FSMS (100%, 10/10) ($p < 0.001$). The analysis showed that inspectors with no knowledge of a food safety standard were of the opinion that there were more inconsistencies than inspectors with at least some knowledge (93%, 13/14 and 67%, 8/12, respectively), although the difference was not statistically significant ($p > 0.05$). Unfortunately, only a few respondents specified how the demands were inconsistent. One FBO commented that the auditor's approach is more theoretical than the inspector's, and one inspector stated that the auditor requires more in general, but not concerning production hygiene issues.

Almost all respondents agreed totally or partly that a certified FSMS could reduce official inspections (Table 3). Both FBOs (11/42) and inspectors (3/28) commented that the frequency of official inspections or inspection time could be reduced (Table 3). However, two inspectors stated that any reductions in official inspections should be preceded by an evaluation of how the FSMS meets the food safety legislation requirements and that the inspector should have access to the criteria used in audits.

3.4. The FBO's perceptions on inspectors' and auditors' expertise and the impact on food safety

The FBOs evaluated the auditors' and inspectors' expertise on food safety legislation as good on average (mean 3.5 and 3.4 respectively) (Fig. 2). Most of the FBOs also totally or partly agreed that auditors and inspectors interpret the requirements of the food safety legislation in a practical way (mean 3.6 and 3.1 respectively) ($p < 0.01$). The FBOs handling food of animal origin assessed the expertise in food safety legislation and the ability to interpret the requirements of the legislation in a practical way better than the FBOs representing other food establishments (Fig. 2). This difference between the establishments handling food of animal origin and other establishments was significant concerning the inspectors' expertise on food safety legislation ($p = 0.046$) and the auditors' expertise on interpreting the requirements of the legislation in a practical way ($p = 0.047$). No significant differences in the answers were observed between the size of the food businesses.

The FBOs evaluated that audits (100% of the FBOs) and official inspections (90% of the FBOs) had improved food safety risk management (Wilcoxon signed ranks test, $p < 0.001$). The food risk management had improved very clearly due to audits, as reported by 30% of the FBOs, and official inspections, as reported by 15% of the FBOs (Fig. 3). The majority of the FBOs' totally or partly agreed that auditors' and inspectors' demands to correct non-conformities/non-compliances were easy to fulfil (84%, 26/31 and 69%, 23/33 respectively) (Wilcoxon signed ranks test $p > 0.05$).

4. Discussion

The study reveals differences between official inspections and audits, which are important to take into account when assessing the utilization of audit results in food control. It is especially important to acknowledge that there were significant differences in the observation of non-compliances in official inspections and non-conformities in audits. The differences were

observed in important self-checking categories, for example, maintenance of the premises and sanitation, which may have serious consequences on food safety.

The observed differences can be due to many reasons, such as the inspectors' and auditors' ability to recognize non-compliances/non-conformities. Discrepancies between official inspections (Läikkö-Roto, Mäkelä, Lundén, Heikkilä, & Nevas, 2015) and between audits (Albersmeier, Schulze, Jahn, & Spiller, 2009) have been observed earlier, but differences in observations between official inspections and audits on site have not been investigated before. Differences in the observation of non-compliances and non-conformities can also arise from the fact that official inspections and audits were not performed at the same time and are a snapshot of a specific point in time (Jacxsens, Kirezieva, Luning, Ingelrham, Diricks, & Uyttendaele, 2015). It is normal that non-compliances occur and are corrected, which means that the situation in the establishment is not identical from one day to another. However, the differences observed in this study were major, the extent and magnitude of the observed differences were surprising, and it is not likely that they can be solely explained by different on-site visit times.

Another factor that can affect the results is the unexpectedness of the official inspections or the expectedness of the audits. Most of the official inspections must be unannounced, but audits have been announced in advance, which may influence the authenticity of the situation at the establishment. To overcome this issue, the conduction of unannounced audits is also being included as a requirement in some standards (Räsänen & Vastamäki, 2016). Further, it can be hypothesised that the expertise of the inspectors and auditors and time available for carrying out official inspections and audits may influence the outcome. Whatever the reasons are for the discrepancy observed between official inspections and audits, it makes comparison of the official inspection and audit results difficult, which poses a challenge to the utilization

of audit reports in food control. Actions to decrease discrepancies could include, for example, joint visits of inspectors and auditors to establishments and availability of the criterion that the auditors use, when assessing findings, to inspectors.

The majority of inspectors stated that there are inconsistencies between the demands of the inspectors and auditors. However, only few inspectors specified what the inconsistencies were, suggesting that most of the inspectors do not have any concrete examples of inconsistent demands. Further, all FBOs not having a FSMS agreed that there are inconsistencies, whereas most of the FBOs that did have a certified FSMS did not agree. These results indicate that inspectors and FBOs not familiar with the topic have a strong impression of audits and official inspections being inconsistent, although in reality this might not always be the case.

Most of the FBOs with a certified FSMS and those few inspectors with some knowledge of a food safety standard agreed that food safety legislation and standards overlap. This is not surprising since most of the respondents also assessed that food safety is sufficiently included in both food safety legislation and standards. Consequently, the majority also agreed that a certified FSMS could reduce official inspections or inspection categories. It seems therefore that Finland has a willingness to utilize the results of audits in official control, as in many other countries (FDA, 2017; Räsänen & Vastamäki, 2016). Suggestions, however, to reduce the frequency of official inspections or reduce control of certain inspection categories should not be made unless the reasons for the discrepancies between official inspection and audit results are investigated. At the moment audit results are not actively utilized in food control in Finland, such as, for example, in Belgium and Denmark (Räsänen & Vastamäki, 2016). However, audits can indirectly influence official inspection results in Finland; if audits result in higher compliance towards food safety legislation, it can lead to decreased inspection

frequency (Evira, 2017).

Both official inspections and audits appear to be important for food safety, as they have impacted food safety risk management according to the FBOs. This finding is in line with previous findings suggesting that official control and certified FSMS improve food safety (Dzwolak, 2016; Escanciano & Santos-Vijande, 2014; Kettunen, Nevas, & Lundén, 2015; Nevas, Kalenius, & Lundén, 2013; Psomas & Kafetzopoulos, 2015; Qijun & Batt, 2016). Audits were assessed in this study to have impacted risk management more than official inspections. The reasons for this were not revealed, but it is possible that longer audit visits compared to shorter official inspections, the content of the audits and official inspections, or the competence of the auditors and inspectors have influenced the FBOs' perceptions of the impact.

The fact that both inspectors and auditors found non-compliances and non-conformities in food establishments is of concern; however, it is not uncommon to find non-compliances in official inspections (Läikkö-Roto et al., 2015; Guiducci, Copeland, Dorsey, & Edelstein, 2011). This indicates that external control is warranted in food establishments, although the FBOs carry the responsibility for the safety of the products. It can also be speculated that more efficacious enforcement measures should be applied due to the high frequency of non-compliances. Time limits for the correction of non-conformities were set systematically in the audits, but in the official inspections time limits were not often used or they were at least not documented. It is possible that some of the non-compliances, for instance, non-compliances concerning hygienic working methods, were requested to be corrected immediately at the official inspection, and therefore a time limit was not documented. The use of time limits is of great importance because they improve the correction of non-compliances (Läikkö-Roto et al., 2015; Luukkanen & Lundén, 2016).

338

339 The FBOs agreed that inspectors and auditors have good expertise in food safety legislation
340 and also assessed positively on average the ability of especially the auditors but also the
341 inspectors to interpret legislative requirements. This is important because it has been shown
342 that FBOs appreciate assistance in interpreting the requirements of legislation (Buckley, 2015;
343 Kettunen, Lundén, Läikkö-Roto, & Nevas, 2017). In this study almost half of the FBOs stated
344 that they need even more information about food safety legislation and its implementation,
345 which is a challenge for inspectors, auditors and possible other players in the field.
346 Interestingly, differences between the opinions on expertise and the ability to interpret
347 requirements in a practical way were seen between the FBOs handling food of animal origin
348 and the other FBOs. The reason for this was not revealed in this study, but it can be
349 hypothesized that the inspectors and auditors visiting establishments handling food of animal
350 origin have more in-depth training due to the risks involved with animal-derived products.

351

352 The results of this study concerning official inspection and audit reports can be generalized to
353 other establishments with some limitations. The number of included establishments was rather
354 small, but the establishments represented different production types, and the official
355 inspections and audits were carried out by several inspectors and auditors. The discrepancies
356 between the findings of inspectors and auditors were also quite striking. The results of the
357 questionnaire must be interpreted carefully because of the scarce number of respondents. The
358 number of responding inspectors is modest, presumably because very few have knowledge of
359 food safety standards. All of the responding FBOs were members of the Finnish Food and
360 Drink Industries' Federation, and therefore we do not know if FBOs that are not members
361 would show a similar answering profile. However, most of the responding FBOs had a
362 certified FSMS. Therefore, we hypothesize that these results can be generalized better to
363 FBOs with a certified FSMS.

In conclusion, official inspections and audits overlap, and both inspectors and FBOs agree that audits of certified FSMSs could somehow reduce official control. However, this study shows striking differences in the observations in official inspections and audits, which makes the comparison of official inspections and audits challenging. The development of a utilization scheme of audit results as part of food control requires a better understanding of the reasons leading to discrepancies between audit and official inspection results.

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Highlights

- Inspectors observed significantly more non-compliances than auditors non-conformities
- All inspectors and 90% of FBOs agree that legislation and standards overlap
- The majority of respondents stated that certified FSMSs could reduce inspections
- Almost half of the FBOs need more information on food safety legislation

Figure captions

Figure 1.

Frequency of non-compliances observed at official inspections (n=66) and non-conformities at audits (n=18).

1=Cross-contamination*; 2=Maintenance*; 3=Hygienic working methods*; 4=Traceability; 5=Contact material; 6=Sanitation*; 7=Temperature control; 8=Pest control; 9=Waste management; 10=Separation of hygiene areas; 11=Personnel health; 12=Sampling*; 13=Self-inspection documentation; 14=By-products; 15=Inspection of received products; 16=HACCP; 17=Reclamations; 18=Recall; 19=Personnel training; 20=Allergen control; 21=Labelling.

*Statistically significant difference in the number of non-compliance observed at official inspections and non-conformities observed at audits (Fisher exact test $p < 0.05$).

Figure 2.

Food business operators' evaluation of the inspectors' and auditors' expertise in food safety legislation and their ability to practically interpret the requirements of the legislation.

*Only FBOs with a certified food safety management system answered.

Figure 3.

Food business operators' assessment of the impact of official inspections and audits.

*Only FBOs that had a certified food safety management system answered.

Figure 1

Figure 2.

Figure 3

Table 1. Number and type of food establishments that provided official inspection and audit reports for the study.

Food business operator	Food establishment	Product type	Food safety management system			
			ISO 22000	ISO TS 22002-1	FSSC 22000	BRC
1	1	Milk powder	1	1		
1	2	Cheese	1	1		
2	3	Meat product	1	1	1	
3	4	Ready-to-eat product	1	1	1	
3	5	Ready-to-eat product	1	1	1	
4	6	Bakery product	1	1	1	
5	7	Processed fishery product	1			
6	8	Meat cutting	1	1	1	
7	9	Processed vegetables	1			
8	10	Cooking oil				1

Table 2. Respondent groups and response rates of the questionnaire and the presence of a certified food safety management system (FSMS) in the responding food businesses.

Respondent group	Number of respondents (%)	Number of food businesses with a FSMS (%)
Food control inspector at local unit	28 ^a	-
Food business operator ^b	42 (16)	31 (74)
Establishment handling food of animal origin	26	20 (77)
Other food premises ^c	16	11 (69)

^aThe questionnaire did not enquire the name of the local food control unit to maintain the anonymity of the inspectors, and therefore the percentage of the responding units cannot be calculated.

^bThe questionnaire was sent to the members (n=260) of the Finnish Food and Drink Industries' Federation. The share of establishments handling food of animal origin and other food establishments among the members is not known.

^cPremises handling vegetables, baking products, candy, beverages, berries, oil or yeast.

Table 3. Food business operators' (FBO) and local food control inspectors' views and the educational needs of food safety legislation and standards.

Statement	Agree completely or partially with the statement % (n/N)		p-value ^a
	FBOs	Local food control	
Food safety			
Food safety is sufficiently included in food safety standards	100 (39/39)	77 (10/13)	< 0.001
Food safety is sufficiently included in food safety legislation	98 (38/39)	96 (25/26)	> 0.05
Food safety is sufficiently included in audits	100 (39/39)	73 (8/11)	< 0.001
Food safety is sufficiently included in official inspections	95 (37/39)	100(26/26)	> 0.05
Overlapping			
Requirements of food safety legislation and standards overlap	90 (28/31)	100 (8/8)	> 0.05
Inspectors and auditors inspect/audit the same issues	81 (26/32)	89 (8/9)	> 0.05
Inspectors' and auditors' demands have been inconsistent	42 (16/38)	81 (21/26)	< 0.001
Certified food safety management system could reduce inspections	93 (27/29)	89 (8/9)	> 0.05
Knowledge and educational needs			
I have basic knowledge about at least one food safety standard	97 (37/38)	48 (13/27)	< 0.001
I need more information about food safety standards	37 (15/41)	86 (24/28)	< 0.001
I need more information about food safety legislation and its implementation	46 (19/41)	33 (9/27)	> 0.05
Food control officials need more information about food safety standards	89 (34/38)	89 (25/28)	> 0.05

^aStatistical significance of the difference between groups was tested with the Mann-Whitney test.