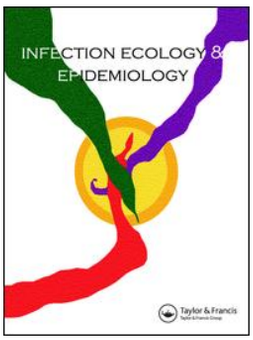

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Non-compliances - an indicator of food control effectiveness

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ABSTRACT

Introduction: This paper presents an option for evaluating food control effectiveness by analysing the frequency of non-compliances (FnC).

Material and methods: A food business establishment can have several different types of control areas (i.e. pest control, HACCP), that can be inspected to assess its compliance with regulations in the food sector. From April 2012 to April 2014, 10 736 inspections were performed in Sweden, covering all 15 types of control areas. In these inspections, 2223 non-compliances were found, giving a FnC of 0.21 per control area inspected. Outlying types of control areas, inspection teams and establishments were selected for supervision of the internal audit procedure.

Results and discussion: The key and surprising finding was that types of control area, teams and establishments with high FnC had a higher ratio of false negative non-compliances than those with low FnC. Moreover, false negative non-compliances were more common than false positive non-compliances. Possible explanations include the complexity of legislation affecting food businesses and the complexities of the food business.

Conclusions: The risk of non-compliance going undetected is greatest where many non-compliances have already been detected. These results should inform future food control strategies.

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Supervision; official control; verification; effectiveness; food business; screening

Introduction

For the consumer, efficient food control means safe, honest and unadulterated foods. For the food business operator (FBO), efficient food control should also ensure fairness in terms of implementation of legislation, foreseeability of food control decisions and level competition with other food businesses. FBOs are responsible for the food safety in their establishments. For national food safety authorities (NFSA), 'effectiveness' is defined as the ability of the NFSA to ensure high quality of official controls (EU Member States Network on National Audit System [NAS]), [1]. Each NFSA must also ensure the quality, impartiality and consistency of official control processes and good cost efficiency. To achieve these aims, the NFSA must carry out internal and external audits and take corrective measures. Furthermore, according to EU regulation EC No. 882/2004 [2], the NFSA must have audit procedures in place to verify the effectiveness of official controls and to ensure that corrective action is taken when needed and that appropriate and up-to-date documentation is available. However, verification of the effectiveness of official controls is an open question, as EU regulations do not prescribe a specific method. To verify the effectiveness of official controls, the Food and Veterinary Office (FVO) of the European Commission (EC) has audited the controls in seven European Union (EU) Member States, with the focus on the control procedures [3]. FVO defines effectiveness as the 'extent to which official controls produce an intended effect and/or achieve an objective' [1]. The objective referred to by FVO is ensuring safe food through official controls that detect non-compliances.

This paper presents one option for evaluating food control effectiveness, namely by analysing the frequency of non-compliances (FnC) with food regulations. The question is whether these non-compliances are false positive or false negative. The efficiency of food control activities is reflected in detection of non-compliances with food safety and quality regulations at food business establishments and subsequent corrective actions. We propose that efficient food control is built on two pillars. The first pillar is that, if complied with, the regulations achieve the objectives of safe food, high food quality, good cost-effectiveness, transparency and absence of fraud, and fair and equitable regulation of food businesses. The second pillar, which is the subject of this paper, is monitoring compliance with the food regulations by different food business establishments. In particular, we examined what FnC actually indicates with regard to food safety regulations. To analyse food control efficiency, the NFSA in Sweden (the National

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Food Agency, NFA) has established an internal audit procedure referred to as supervision [4,5]. The first step in the supervision procedure is statistical screening to detect outliers in FnC for different determinants, such as categories of establishments, types of control areas and different inspection teams. Thereafter, for a selected sample of these identified outliers (high or low FnC values), a team of skilled inspectors (supervisors) re-examines the findings through examination of written procedures and performance, documentation of control and inspections of the premises.

The present paper focuses on the outliers, i.e. food business establishments with either a high FnC or a low FnC, looking at the type of control area, the category of establishments and the different inspection teams. A high frequency could indicate actual problems with compliance or too strict inspections, while a low frequency could indicate good compliance or lax inspections.

Material and methods

Organisation of official food controls by the NFA

The NFA has four regional food control divisions, each of which is divided into local inspection teams consisting of 6–15 food control inspectors. In 2014, the NFA had 220 full-time employees, allocated to 17 local inspection teams.

Categories of establishments and risk classes

The NFA had oversight of around 850 food establishments in 2013, including those approved according to EU regulation EC No. 853/2004 [6]and other registered food production establishments such as wine and spirits producers, and railway and aircraft catering. The approved establishments are categorised according to the European Commission Technical Specification [7] (Table 1). Furthermore, the establishments are classified into risk classes based on the volume of products produced, the type of food and the type of processing activity [8]. Establishments with more than one food processing activity are categorised as posing the highest risk. The calculation of inspection hours for establishments in different risk classes has been risk-based since 2007 [8]. Thus, more inspection hours are allocated to food establishments with activities representing a higher risk or with larger production volumes. Furthermore, to comply with legal obligations, the NFA has published a control manual [9] that serves as a guideline for competent food safety authorities in Sweden. The manual points out that the general objective for the competent authorities (safe food and risk-based, legally secure and effective controls) should be achieved by detecting non-compliances at food business establishments. The Food Control Department at the NFA has also issued instructions for the supervision of official inspections, in order to evaluate written guidelines, verify compliance with written guidelines and, through analysis of the results, assess the effectiveness of official food controls [4].

Types of food control areas

In Sweden, the official food control inspection of an establishment may include one or more of 15 different types of food control areas. These are: 1) Layout, design, construction of food premises and equipment; 2) raw materials and packaging materials; 3) handling, storage and transport of foods; 4) handling and storage of waste; 5) pest control; 6) cleaning and disinfection; 7) water supply; 8) temperature control; 9) personal hygiene; 10) training; 11) hazard analysis and critical control plan (HACCP); 12) food information and labelling; 13) traceability; 14) microbiological criteria; and 15) other requirements. There are additional, more specific, types of control areas for slaughterhouses and meat cutting plants. However, these specific types of control areas and area 15 ('other requirements') were excluded from the present analysis.

Study period and population

During the study period, from April 2012 to April 2014, 10,736 control areas were inspected and 2223 non-compliances were found, giving an overall frequency of non-compliance of 0.21 per control area inspected (Table 1).

Reporting official food control inspections

In 2012, the NFA launched a monitoring system for reporting official food control inspections. The results of official inspections are documented using an internet-based application and contain information about the date, attendance, control areas inspected, non-compliances found, etc., together with basic facts about the establishment. During the study period, the system was operational in terms of reporting results from official control inspections. Inspection results relating to approval of establishments, ad hoc inspections, and additional official inspections were excluded.

Performance of supervision

The present study was based on statistical screening of the FnC results followed by supervision for selected outlying official food inspections, as described by Berking et al. [4,5]. In this procedure, supervisors reassess the performance of official inspections and the findings obtained and compare their findings against the initial findings reported by the inspection team.

Table 1. Frequency of non-compliances for different categories of food business establishments in Sweden, April 2012-April 2014. Bold text indicates categories outside the 95% confidence interval (CI) of the mean frequency of non-compliances. Highlighted categories* of establishments were selected for the supervision procedure.

Category of establishment	Number of inspected control areas	Number of non-compliances	Frequency of non-compliances
Factory fishing vessel, fishery*	**223**	**0**	**0.00**
Cold/freezer storage	**7**	**0**	**0.00**
Milk powder	**44**	**0**	**0.00**
Egg packing*	**1501**	**91**	**0.06**
Freezing, non-integrated	**38**	**3**	**0.08**
Cold storage, non-integrated	**86**	**7**	**0.08**
Blood products	**10**	**1**	**0.10**
Unknown	**95**	**10**	**0.11**
Grocery store, integrated	**28**	**3**	**0.11**
Gelatine production	18	2	0.11
Rewrapping, non-integrated	173	20	0.12
Wild game slaughter	802	122	0.15
Prepared fishery products	280	44	0.16
Freezer storage non-integrated	104	18	0.17
Unspecified establishments	63	11	0.17
Egg products	40	7	0.18
Transport	33	6	0.18
Milk products	576	106	0.18
Meat preparation	257	48	0.19
Cutting	776	165	0.21
Minced meat	324	72	0.22
Meat products*	**2194**	**564**	**0.26**
Unprepared fishery products	**196**	**52**	**0.27**
Purification of bivalve molluscs	**21**	**6**	**0.29**
Slaughter*	**2771**	**833**	**0.30**
Dispatch of bivalve molluscs	**25**	**8**	**0.32**
Rewrapping, integrated	**31**	**13**	**0.42**
Wholesale fishery products	**20**	**11**	**0.55**
Total	10,736	2223	0.21

This approach has the advantage of making direct observations and evaluations on the same site and in the same situation as covered in the ordinary food inspection, because the supervisions are carried out concurrently with the official inspections.

Metrics used

In each food establishment, one or more control areas might be inspected. For each of these control areas, zero, one or more non-compliances were recorded in this study. The unit of interest in the study was the frequency of non-compliances (FnC), as defined in Equation 1.

$$\text{FnC} = \text{Number of non} - \text{compliances} / \text{Number of food control areas inspected} \quad (1)$$

For every supervision made on inspections taking place at establishments, the outcome can be true or false non-compliance and false non-compliance can be positive or negative. During the supervisions selected for this study, the food establishment was inspected and the results were compared with those of the ordinary inspection, using two metrics expressing the relative magnitude of false positive and false negative results (Equations 2 and 3).

$$\text{Frequency of false negative non} - \text{compliances} = \text{Number of false negative non} - \text{compliances} / \text{Number of supervision visits} \quad (2)$$

$$\text{Frequency of false positive non} - \text{compliances} = \text{Number of false positive non} - \text{compliances} / \text{Number of supervision visits} \quad (3)$$

Selection procedure for supervision

The selection of categories of establishments, teams and types of control areas for supervision was based on the following four-step procedure:

Selection of categories of establishments

The first step was aimed at detecting outliers or categories of establishments with FnC outside the 95% confidence interval (CI) of the mean. These outliers are shown in Table 1 as bold text. The second step was to scrutinise the selected categories of establishments with regard to their importance, defined as number of control areas inspected per category. Thus slaughterhouses and meat product plants were identified as establishments with high FnC, while egg packing plants and factory fishing vessels were identified as establishments with low FnC.

Selection of inspection teams

The third step was selection of inspection teams from amongst those used in inspecting the selected categories of establishments. For egg packing plants, slaughterhouses and meat product plants, the mean and 95% CI of the FnC were calculated for each inspection team, and teams with FnC values outside

Table 2. Egg packing plants. Frequency of non-compliances for different food control inspection teams. Bold text indicates teams outside the 95% confidence interval (CI) of the mean frequency of non-compliances. Highlighted* teams were selected for the supervision procedure.

Team	Number of inspected control areas	Number of non-compliances	Frequency of non-compliances
Team A	**7**	**0**	**0.00**
Team B*	**140**	**0**	**0.00**
Team C*	**124**	**1**	**0.01**
Team D*	**318**	**5**	**0.02**
Team E	**50**	**1**	**0.02**
Team F*	**114**	**3**	**0.03**
Team G	68	3	0.04
Team H	111	7	0.06
Team I	89	7	0.08
Team J	117	11	0.09
Team K	189	19	0.10
Team L	34	4	0.12
Team M*	**58**	**9**	**0.16**
Team N	**5**	**1**	**0.20**
Team O*	**77**	**20**	**0.26**
Total	1501	91	0.06

the 95% CI were selected for each previously selected category of establishment (Table 2–4). In the study period (April 2012-April 2014), this comprised two teams with high FnC and five teams with low FnC.

Selection of the type of control areas

The fourth step was selection of types of control areas amongst the selected category of establishments and the selected inspection teams. For slaughterhouses and meat product plants, mean FnC and its 95% CI were calculated for each type of control area. The types of control areas with FnC values outside the 95% CI were identified (Table 5, 6). For practical reasons, the selection for supervision was limited to the types of control areas planned to be inspected during 2015. For slaughterhouses, raw materials and packaging materials were

Table 3. Slaughterhouses. Frequency of non-compliances for different food control inspection teams. Bold text indicates teams outside the 95% confidence interval (CI) of the mean frequency of non-compliances. Highlighted* teams were selected for the supervision procedure.

Team	Number of inspected control areas	Number of non-compliances	Frequency of non-compliances
Team D*	**90**	**9**	**0.100**
Team F	190	31	0.163
Team J	237	41	0.173
Team E	106	29	0.274
Team M	87	24	0.276
Team A	79	22	0.278
Team H	253	73	0.289
Team P	277	84	0.303
Team K	227	74	0.326
Team N	228	77	0.338
Team B	177	60	0.339
Team I	302	103	0.341
Team C	162	60	0.370
Team G	51	19	0.373
Team L	146	55	0.377
Team O*	**159**	**72**	**0.453**
Total	2771	833	0.301

Table 4. Meat product plants. Frequency of non-compliances for different food control inspection teams. Bold text indicates teams outside the 95% confidence interval (CI) of the mean frequency of non-compliances. Highlighted* teams were selected for the supervision procedure.

Team	Number of non-compliances	Number of inspected control areas	Frequency of non-compliances
Team D*	**55**	**4**	**0.073**
Team P*	**33**	**4**	**0.121**
Team G	258	44	0.171
Team Q	33	6	0.182
Team J	173	35	0.202
Team F	128	28	0.219
Team H	27	6	0.222
Team L	191	44	0.230
Team N	69	16	0.232
Team B	21	5	0.238
Team C	187	46	0.246
Team A	15	4	0.267
Team I	89	26	0.292
Team M	300	91	0.303
Non specified	13	4	0.308
Team K	422	137	0.325
Team E	75	25	0.333
Team O*	**105**	**39**	**0.371**
Total	2194	564	0.257

Table 5. Slaughterhouses. Frequency of non-compliances for control areas. Bold text indicates control areas outside the 95% confidence interval (CI) of the mean frequency of non-compliances. Highlighted* control areas were selected for the supervision process.

Control area	Number of inspected control areas	Number of non-compliances	Frequency of non-compliances
Traceability	**199**	**13**	**0.065**
Water supply	**73**	**9**	**0.123**
Raw materials and packaging materials*	**271**	**34**	**0.125**
Training	15	2	0.133
Handling and storage of waste	199	37	0.186
Temperature control	212	42	0.198
Handling, storage and transport of foods	365	126	0.345
Microbiological criteria	**236**	**82**	**0.347**
Personal hygiene	55	20	0.364
Food information and labelling	**305**	**111**	**0.364**
Pest control	156	58	0.372
Cleaning and disinfection	265	106	0.400
HACCP	243	103	0.424
Layout, design, construction of food premises and equipment	**177**	**90**	**0.508**
Total	2771	833	0.301

the type of control areas selected for supervision. For meat product plants, HACCP, food information and labelling, personal hygiene and training were selected. For the categories of establishments with low frequency of non-compliances (egg packing plants and factory fishing vessels), there were insufficient data to select types of control areas. For these establishments, all planned control areas were selected for supervision. The screening process identified 22 official inspections, including at least 45 control areas that should be supervised.

Table 6. Meat product plants. Frequency of non-compliances for different control areas. Bold text indicates control areas outside the 95% confidence interval (CI) of the mean frequency of non-compliances. Highlighted* control areas were selected in the screening process.

Control area	Number of inspected control areas	Number of non-compliances	Frequency of non-compliances[a]
Training*	**10**	**0**	**0.000**
Water supply	**57**	**3**	**0.053**
Traceability	**172**	**10**	**0.058**
Personal hygiene*	**17**	**1**	**0.059**
Temperature control	**135**	**8**	**0.059**
Raw materials and packaging materials	263	31	0.118
Handling and storage of waste	133	28	0.211
Microbiological criteria	212	50	0.236
Pest control	114	29	0.254
Handling, storage and transport of foods	296	80	0.270
Cleaning and disinfection	**141**	**50**	**0.355**
HACCP*	**207**	**76**	**0.367**
Food information and labelling*	**278**	**124**	**0.446**
Layout, design, construction of food premises and equipment	**159**	**74**	**0.465**
Total	2194	564	0.257

On-the-spot supervision

On-the-spot supervision was performed on the teams, categories of establishments and types of control areas selected according to the statistical selection process and selection criteria described above. The supervisor informed the inspection teams to be supervised about the establishments and types of control areas that had been chosen for the supervision. The team manager appointed members of the team to attend the supervision. The supervision was made as one inspection visit. During the inspection, one or more control areas were supervised. The supervisor participated as a passive observer during the official inspection procedure and examined the documentation for the actual food control inspection. The supervisor also evaluated the performance of the food control inspection procedure and subsequent documentation. False negative non-compliance frequencies (Eq. 2) were recorded by the supervisor, as they indicated that the initial inspection did not detect non-compliance, did not further investigate non-compliance or detected non-compliance but assessed it as being in compliance. False positive non-compliance frequencies (Eq. 3) were also recorded by the supervisor, as they indicated that the initial inspection had wrongly assessed observations during inspection as being in non-compliance or that the assessment had insufficient legal support. These supervision findings were discussed with the inspection team members before being presented to the group of supervisors. The supervisions were then documented in a separate report addressed to the team manager and the head of division. Of the 22 selected official food control inspections, 21 were subject to on-the-spot supervisions during 2015. One supervision could not be carried out due to unavailability of a supervisor. Data collected from the on-the-spot supervisions and preparation process were analysed for differences between teams, categories of establishments and types of control areas.

Data analysis

For statistical analyses, Fisher´s exact test was used.

Results

The results are presented in Table 1–6 and Figure 1–3.

In 11 out of 21 supervisions, false non-compliances were found. In total, there were 25 false non-compliances, of which 22 (88%) were false negatives

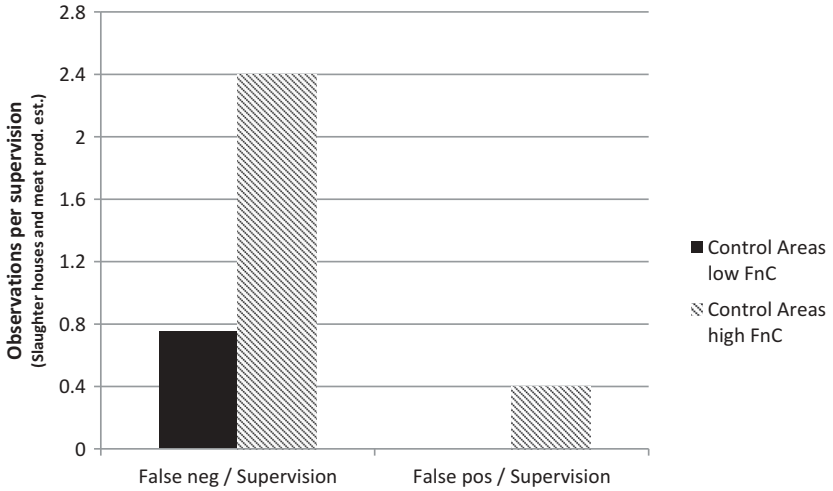

Figure 1. Frequency of observations judged false negative (neg) and false positive (pos) per supervision in control areas with a high and low frequency of non-compliances (FnC). The results do not include categories of establishments with a low frequency of non-compliances.

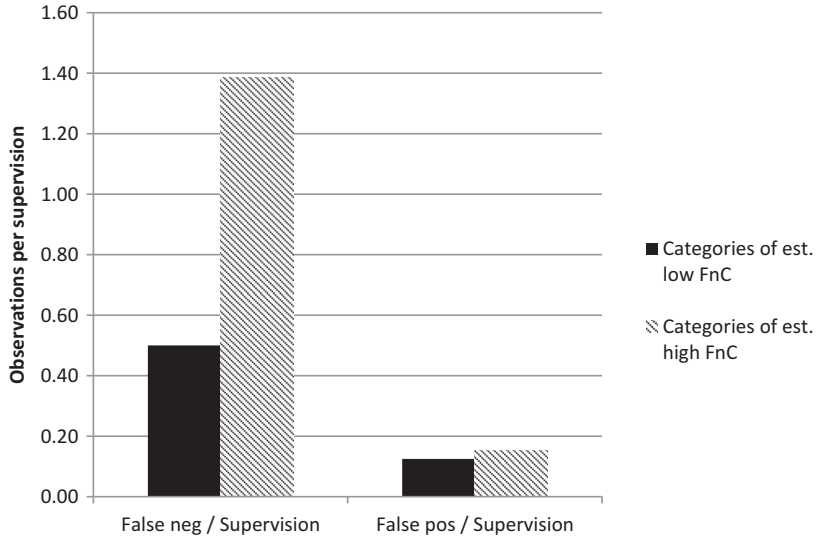

Figure 2. Frequency of observations judged false negative and false positive per supervision in categories of establishments (est.) with a high and low frequency of non-compliances (FnC).

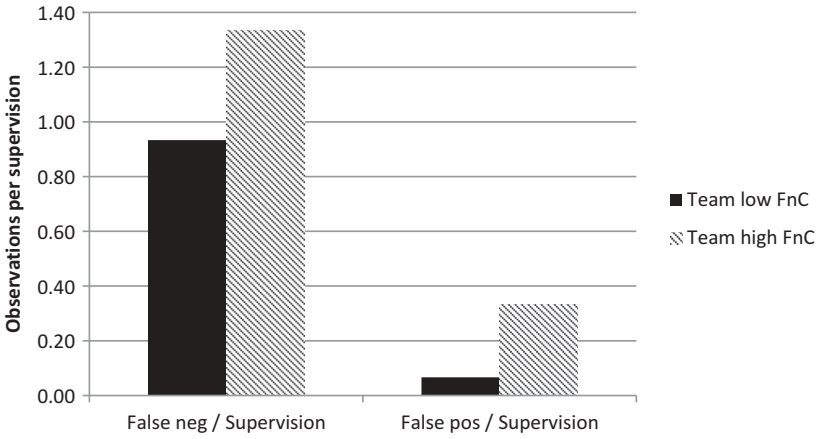

Figure 3. Frequency of observations judged false negative (neg) and false positive (pos) in supervisions of food control inspection teams with a high and low frequency of non-compliances (FnC).

and only three (12%) were false positives. In most cases, only 1–2 false non-compliances per supervision were found (nine of 11 supervisions), while in two supervisions there were six and seven false non-compliances, respectively.

The frequency of false negative non-compliances was higher for types of control areas with high FnC (2.4) than for control areas with low FnC (0.75) (Figure 1), but there was no significant difference between types of control areas. In slaughterhouses and meat product plants (high-risk establishments) 20 false non-compliances were found, of which 18 were false negative and two were false positive. For control areas with high FnC, the actual number of false negatives and false positives was 12 and 2, respectively. For control areas with low FnC, the corresponding values were 6 and 0, respectively.

The frequency of false negative non-compliance was higher for categories of establishments with high FnC (1.38) than for establishments with low FnC (0.50) (Figure 2), but there was no significant difference between categories of establishments. The number of false positives was 1 and 2 for categories of establishments with low and high FnC, respectively, while the number of false negatives was 4 and 18 for categories of establishments with low and high FnC, respectively.

The frequency of false negative non-compliances was higher for teams with high FnC (1.33) than for teams with low FnC (0.93) (Figure 3). The absolute number of false positive non-compliances was small, one for teams with low FnC and two for teams with high FnC.

Discussion

The key finding

The key and somewhat surprising finding was that types of control areas, teams and establishments with high FnC had a higher ratio of false negative non-compliances than teams, establishments and

control areas with low FnC. Moreover, false negative non-compliances were much more common than false positive non-compliances. This means that the current food control inspection system is failing to detect all non-compliances, in particular in problem settings. There is thus a need to analyse the determinants of these false non-compliances. We interpret these findings as supporting the claim that deficiencies in food control effectiveness can arise more often in types of control areas and establishments with high FnC. The results also illustrate that FnC can be used as one of several indicators for concerns or higher risks in terms of food safety. A high FnC for a type of control area or establishment indicates that the FBO has not succeeded in meeting the statutory requirements for that control area or establishment. A high FnC can also indicate a greater underlying problem, since supervision of official inspections found a high frequency of non-compliances not identified by the official inspections.

Types of control areas

Most false negative non-compliances were found in types of control areas with high FnC. Complexity could be the main reason for this, as control areas with high FnC (HACCP and food information and labelling) are more complicated to inspect than those with low FnC (personal hygiene and training). HACCP is a broad type of control area and covers both the food production process and process-specific hazards, which vary widely depending on what is produced. Food information and labelling are covered by a broad range of legislation and involve activities such as prevention of food fraud, mandatory food information and protection of designations of origin, nutrition and health claims, weights and volumes. During the supervision performed in the present study, most false non-compliances were found in control areas with high FnC, i.e. the inspectors did not identify all non-compliances in the more complex types of control areas.

According to the supervisors, lack of sufficient experience among food control inspectors is also a determinant for false negative non-compliances. A possible explanation is that inspectors need broader knowledge about production processes and process-specific hazards and more experience in order to perform accurate food control inspections in complex settings.

Teams

The findings were similar for all teams studied. A possible explanation for the relatively small difference in ratios between the teams is that the composition of the teams changed over time, thereby levelling out any differences, while the categories of establishments and the control areas remained the same.

According to Läikkö-Roto et al. [10], introduction of new inspection staff may impair the quality and efficacy of official food controls. Our results supported that finding, as results from two particular supervisions contributed nearly 60% (13 of 22) of the observed false non-compliances. In both cases, the controls were performed by inspectors with little experience of the actual type of control area or establishment. One of these supervisions was performed at a team with high FnC (seven false non-compliances) and the other at a team with low FnC (six false non-compliances). These findings support the hypothesis that the assessment of observations made during official food control inspections is dependent on the individual inspector's knowledge and experience [11]. Official controls at establishments with complex types of control areas, i.e. high FnC, require highly experienced and trained inspectors. The first author has also experienced that inspectors tend to report less non-compliances if they already found non-compliances. Especially minor non-compliances can be under-reported. In future inspections, one priority should be to ensure that the teams are well-balanced in terms of sufficient experience and knowledge.

Establishments

Establishments with high FnC (slaughterhouses and meat product plants) have more complex production processes than establishments with low FnC (egg packing plants and factory fishing vessels). Slaughter and meat processing both involve intensive manipulation and handling of meat and, since many foodborne pathogens can be harboured in the gastrointestinal tract of food-producing animals, there are significant risks of cross-contaminations during handling. Egg packing plants in Sweden only handle eggs from hens and there are few hazards during processing, so eggs are eaten whole have a limited risk of cross-contamination. Factory fishing vessels in Sweden only handle shrimps, which are boiled after capture at sea.

There is also a difference in complexity in the regulations between high FnC and low FnC establishments, in that it is more difficult for a slaughterhouse or meat product plant to ensure that its complex food production processes comply with the food regulations. Complex food business establishments often have to follow complex regulations, so there is a correlation with control areas. Furthermore, since high FnC establishments have higher risks in their production, they are categorised as high-risk establishments, which results in more inspection hours and consequently more frequent and longer inspections than for low-risk establishments. In future assessments, the importance of considering the

complexities in establishments and in regulations when interpreting the results of FnC should be borne in mind. Comparisons of FnC between different categories of establishments can be biased due to differences in complexity, while comparisons within a category of establishments should be easier to interpret.

What is effectiveness?

We could not find any published information on to measure the effectiveness of official food controls using the definition of effectiveness defined by NAS, i.e. the extent to which official controls produce an intended effect and/or achieve an objective such as consumer food safety. A study in Finland [12] approached the subject by evaluating official food controls and found that the use of checklists and templates for inspection reports enhanced the consistency and efficacy of inspections. The templates also reduced the time required and increased the quality of reporting. Time limits for correcting non-compliances at food business establishments had a significant effect on the efficacy of controls [12]. Those authors concluded that food control efficacy is determined by the extent of correcting non-compliances.

In another study in Finland [10], the prerequisites for effective official food control were investigated. This revealed that the competent authorities invest in creating adequate working conditions through the provision of guidance papers, pro forma templates and possibilities for staff to collectively hold discussions. However, poor orientation, tacit knowledge and incomplete commitment among staff to quality systems are persistent challenges in food control units. Insufficient human resources and the inability of heads of food control units to recognise problems in the workplace setting may further impair the functional capacity of these units [10]. One example of the importance of setting relevant objectives is the finding that the publicly accessible rankings (smileys) do not represent the microbiological content, and consequently the risks to consumers, of the products originating from sushi bars [13].

In order to measure the effectiveness of food controls, the objectives of these controls should be set to focus on safe food and reliable detection of non-compliances with food safety regulations at food business establishments. Guidance for effectiveness criteria should be derived from the food safety legislation, which aims to (a) ensure safe food production, but also to (b) combat food fraud, (c) ensure fair competition between food business operators and (d) confirm that food information is reliable. Different parts of the regulations have differing importance for the production of safe food and fair information practices. Hence, supervision should validate the effectiveness of future official controls.

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