

AUDIT
REPORT

Follow-up and Close-out
of Non Compliances with
Food Law in Local Authorities
– Roscommon County Council

JUNE 2012



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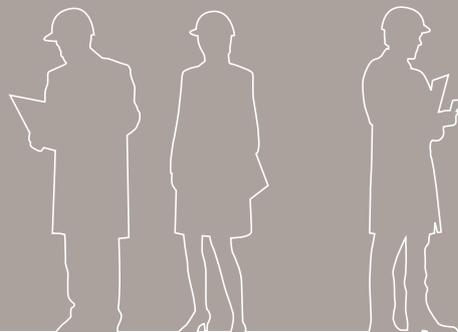


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1. GLOSSARY

CVO	County Veterinary Officer
FBO	Food Business Operator
FSAI	Food Safety Authority of Ireland
FVO	Food and Veterinary Office
LAVI	Local Authority Veterinary Inspector
LAVS	Local Authority Veterinary Service
SOP	Standard Operating Procedure
TVI	Temporary Veterinary Inspector

2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland is responsible for the enforcement of all food legislation in Ireland, which is carried out through service contracts with official agencies. As part of its legal mandate, the Food Safety Authority of Ireland is required to verify that the system of official controls is working effectively. For the purposes of assessing the delivery of official controls by the local authority veterinary service, the follow up and close out of non compliances against the requirements of food law identified during official control inspections was audited. This audit with Roscommon County Council was one in a programme of five audits relating to follow up and close out of non compliances.

The first day concentrated on an audit of paperwork associated with official controls, with an emphasis on follow up and close out of non compliances. A total of 12 establishment files were examined by the audit team, which included 2 establishments in which enforcement action had been taken. The second day of the audit involved on-site verification in two food business establishments, which included an assessment of the status of the non compliances which had been identified during official control inspections.

Within the Roscommon County Council functional area, there are 17 food establishments, which are supervised by the local authority veterinary service. Sixteen of these establishments are fully approved, and one has recently been conditionally approved. It was noted that where significant non compliances were identified, follow up inspections took place. The audit team examined the records of such inspections and noted that the information relating to the non compliances identified as well as the corrective actions, taken by the food business operators, should be more detailed. The audit team observed that these are official control records and more detail in relation to the close out of non compliances by FBOs would be necessary to verify the enforcement of food law.

Two establishments were selected for on-site verification; in which non compliances were noted, but no formal enforcement action was taken. In the first establishment, seven non compliances were assessed by the audit team, which had been noted during the preceding nine inspections. During the on-site verification activity, the audit team verified that two of these non compliances had been fully addressed and two had been improved but required further attention and three non compliances were outstanding or had recurred at the time of this audit.

In the second establishment, the audit team examined the status of 13 non compliances; which had been identified during the preceding 8 inspections. The audit team confirmed that seven of these thirteen non compliances had been fully addressed, three had been improved but required further attention and three non compliances were outstanding or had recurred at the time of this audit.

A review of inspection outcomes confirmed that when significant non compliances were identified during official control inspections; follow up action, including enforcement action was taken. The audit team noted that follow up in relation to non compliances, identified during official control inspections, was recorded, but that additional detail relating to the non compliances identified as well as the corrective actions, taken by the food business operators, should be maintained on subsequent inspection reports.

The audit team were of the opinion that both establishments selected for on-site verification, as part of this audit, were operating, on the day of the audit, in line with the requirements of the approval for the establishment. In general, both establishments were operating at a standard required for an approved establishment. However, the audit team noted a number of non compliances which require corrective action, in the first establishment. The audit team noted that official controls were generally being applied in a satisfactory manner in the two establishments audited as part of the audit. However, it was noted that in the first establishment that 42.8% of the non compliances assessed by the audit team were outstanding or had recurred.

3. INTRODUCTION

The Food Safety Authority of Ireland (FSAI) is responsible for the enforcement of all food legislation in Ireland. The FSAI carries out this enforcement function through service contracts with official agencies. These service contracts outline an agreed level and standard of food safety activity that the official agencies perform as agents of the Authority. Roscommon County Council (the local authority) has entered into a service contract with the FSAI. The local authority, through the local authority veterinary service (LAVS), is responsible for the implementation and enforcement of national and EU legislation as it applies to establishments under their supervision. It is a requirement of the service contract that the local authority shall ensure that official controls are carried out regularly; on a risk basis, and with appropriate frequency.

As part of its legal mandate, and in accordance with schedule 5 of the service contract, the FSAI is required to verify that the system of official controls is working effectively. For the purposes of assessing the delivery of official controls by the LAVS, and in light of a finding from the Food and Veterinary Office (FVO) General Audit in 2008¹ relating to follow up actions, it was decided to audit the follow up and close out of non compliances against the requirements of food law identified during official control inspections. Compliance by the local authority with regard to relevant food legislation, adherence to the terms and requirements of the FSAI service contract as well as conformance with relevant documented procedures was assessed.

This audit with Roscommon County Council was one in a programme of five audits to assess the follow up and close out of non compliances within the LAVS. This report describes the audit objective, scope, methodology and the findings from the audit of Roscommon County Council.

3.1. Audit Objective

The objective of this audit was to assess the implementation of official controls in approved establishments supervised by the LAVS. The audit focused on follow up and close out of non compliances identified during official control inspections.

¹ General Audit Ireland 2008 - DG(SANCO)/2008-8724

3.2. Audit Scope

FSAI audits of official controls involve verifying compliance by official agencies with regard to relevant legislation and adherence to the FSAI Service Contract, as well as relevant Guidance Notes and Codes of Practice. This audit assessed the follow up and close out of non compliances against the requirements of food law identified during official control inspections. Additionally, on the spot confirmation at two approved food establishments took place, in order to verify implementation of the necessary supervisory arrangements and to assess the follow up and close out of non compliances identified during official control inspections.

3.3. Audit Criteria and Reference Documents

During the audit, the audit team assessed compliance with the audit criteria, which included:

- The FSAI Service Contract (including the FSAI Act)
- Roscommon County Council Business/Service Plans & data supplied to FSAI
- Documented procedures for the LAVS
- Regulation (EC) No. 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- Regulation (EC) No. 852/2004 on the hygiene of foodstuffs, as amended
- Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin, as amended
- Regulation (EC) No. 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, as amended
- Regulation (EC) No. 882/2004 on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs, as amended
- SI 432/2009: European Communities (Food and Feed Hygiene) Regulations, 2009
- Guidance Notes/Codes of Practice and other relevant legislation detailed in the FSAI Service Contract

3.4. Audit Methodology

This audit of official controls was undertaken using documented procedures which are included in the FSAI Quality Management System, namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI audit obligations, defined in schedule 5 of the service contract between the FSAI and Roscommon County Council, and are in accordance with the requirements of Regulation (EC) No. 882/2004 (including Article. 6.1 of Commission Decision 2006/677/EC) and the FSAI Act.

A pre-audit questionnaire was forwarded to Roscommon County Council. The purpose of the pre-audit questionnaire was to collate and confirm information regarding official controls and documented procedures within Roscommon County Council's functional area.

An evaluation plan was then developed, which provided a detailed overview of the audit; including audit scope, objectives, criteria and team. The evaluation plan also included a proposed itinerary for on-site activity.

The on-site activity took place on Tuesday, July 26th & Wednesday, July 27th 2011. The first day was spent on desktop activities; commencing with an opening meeting to explain the objective of the audit, the audit methodology and how the audit findings would be reported. The desk top element of the audit involved a review of the information provided as part of the pre-audit questionnaire as well as an audit of paperwork associated with official controls; with an emphasis on follow up and close out of non compliances. As part of the audit; the actions taken, arising from non compliances identified during the course of official control inspections, from January 2010 to the time of this audit, were assessed. This evaluation included assessment of compliance with the requirements of the:

- legislation,
- service contract between the FSAI and Roscommon County Council, including Guidance Notes and Codes of Practice and
- LAVS documented procedures

Establishment files were used to provide evidence of activity relevant to follow up and close out of non compliances, as appropriate. A total of 12 establishment files were examined by the audit team, which included 2 establishments in which enforcement action was taken. Enforcement action is taken to mean an enforcement taken under the FSAI Act, the European Communities (Food & Feed Hygiene) Regulations, 2009 (SI 432 of 2009) or a prosecution.

This evidence included:

- inspection reports for official control inspections,
- records of enforcement actions taken, including prosecutions and enforcement actions taken under the FSAI Act (closure orders, etc)

The second day of the audit involved on-site verification in two food business establishments, which included an assessment of the status of the non compliances which had been identified during official control inspections.

A closing meeting was held at the end of the second day; the purpose of which was to outline the main findings from the audit. The findings were discussed and the local authority was provided with an opportunity to provide clarification and / or additional information, as well as providing feedback on the audit.

4. OFFICIAL CONTROLS PERFORMED IN ACCORDANCE WITH REGULATION 882/2004

4.1. Organisation and Structure of Official Controls

The LAVS provides a range of food safety / food control services in accordance with the service contract between the local authorities and the FSAI. These services include inspection of relevant food businesses together with food sampling to ensure compliance with food law and management of food alerts and outbreaks. The local authorities are autonomous bodies with no formal regional structure. Official control services are delivered by the CVO, with the assistance of temporary veterinary inspectors (TVIs).

Within the Roscommon County Council functional area, there are 16 approved food establishments, which are supervised by the local authority. There is another establishment which had recently been granted conditional approval and the paperwork for this approval was being finalised, at the time of this audit. The details of the inspection outcomes and records for official control inspections undertaken in the 17 establishments were made available to the audit team. The FSAI holds a register of local authority supervised establishments and it was noted that the 16 approved establishments were on the FSAI register.

4.2. Coordination and Planning of Official Controls

The target for frequency of inspection is based on risk assessments which have been undertaken in respect of establishments in Roscommon County Council's functional area. Official control inspections are unannounced, as much as possible.

From the establishment files reviewed, the audit team noted that where significant non compliances were identified during official control inspections; that additional inspections were carried out. The audit team noted that after enforcement action had been taken; follow up inspections were carried out to ensure that the non compliances had been closed out.

4.3. Risk Categorisation

Article 3 of Regulation (EC) No. 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so, account must be taken of identified risks that may influence food safety, past records of FBOs, the reliability of own checks and any additional information on non compliance.

The LAVS use the standard operating procedure (SOP), D25: Risk Assessment of Establishments, to assess the risk associated with food establishments under their supervision. This SOP guides the user through a risk assessment process, which includes assessment of the types of processes being undertaken, as well as animal health & welfare, throughput in the establishment and FBO skill, training, and compliance with food law. Following this assessment, a risk category is assigned which allows the nature and intensity of official controls to be determined.

The audit team examined whether or not a risk assessment had been carried out in order to determine the nature and intensity of official controls, for each approved establishment in Roscommon County Council's functional area. Both establishments selected for on-site verification audits, had been categorised as high risk.

The audit team were advised of the risk assessment outcome for 16 of the 17 establishments and noted that a record of the risk assessment outcome was maintained in 11 of the 12 establishment files examined as part of the audit. The audit team noted that the risk had been re-assessed as part of the annual or biannual audits, which had taken place recently in some establishments, and a record of this was maintained in the establishment file. No risk assessment had been carried out in relation to the remaining establishment.

Table 1: Food Establishments by Risk Category

Risk Category	Number of establishments
Very High	0
High	4
Medium	8
Low	4
Not assessed	1
Total	17

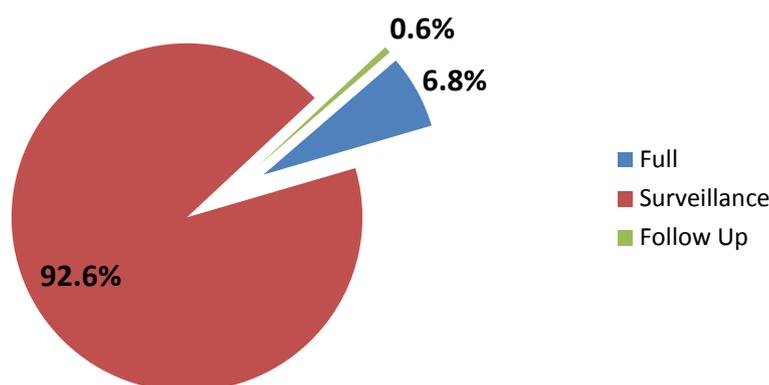
4.4. Frequency of Official Controls

In Roscommon County Council, the target for frequency of inspection is based on the results of the risk assessment for official controls. The audit team were advised that inspections were, on average, undertaken on a monthly basis in most establishments, with low risk establishments being inspected once every two to three months. Establishment files examined verified that the frequency, as detailed in SOP D25 (Risk Assessment) is generally being complied with.

As part of the audit, information was examined, relating to the numbers and outcome of inspections which had taken place, in the 12 approved establishments assessed as part of this audit. A total of 161 official control inspections were carried out between January 2010 and June 2011, in the 12 establishments.

The audit team noted that there were ten inspection reports in which the inspection type had not been recorded. The local authority advised that these would have been surveillance inspections. The audit team noted that there were a number of inspections which took place in slaughterhouses, which were “slaughterhouse audit for non slaughter days” or “slaughterhouse audit for slaughter days”, as is provided for in SOP A6: Slaughterhouse Inspections / Audits. By agreement, the audit team has reported these inspections as “surveillance inspections”. In figure 1, below, 24% of the surveillance inspections constitute these inspections.

Figure 1: Official Control Inspections from January 2010 to June 2011, by Inspection Type²



²These are inspections carried out in the 12 approved establishments which were assessed as part of this audit.

From the establishment files reviewed, the audit team noted that where significant non compliances were identified during official control inspections; additional inspections were carried out. The review of the inspection records for official control inspections following enforcement action, demonstrated that follow up inspections were carried out.

4.5. Documented Procedures

Article 8 of Regulation (EC) No. 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures containing information and instructions for staff and must keep these procedures up-to-date.

The purpose of the LAVS standardisation working group is to develop and review standard operating procedures (SOPs) to be followed by local authority veterinary inspectors (LAVIs) while carrying out official controls. There are a number of SOPs, which have been developed by the LAVS standardisation working group, which are relevant to this audit. These include:

- QP 1: Non Compliance Procedure
- D1: Auditing of a HACCP System
- D4: Procedure for Issuing a Legal Notice for Enforcement
- D11: Preventative Maintenance Programme
- D25: Risk Assessment of Establishments
- M2: Hygiene Inspections of Establishments
- A6: Slaughter house Inspections / Audits

The audit team noted that Roscommon County Council makes use of the SOPs detailed above, and the review of the establishment files provided evidence of this. In particular, the risk assessment carried out in respect of 11 of the 12 establishments assessed; the form, which is provided as an appendix to the SOP D25 (Risk Assessment of Establishments), had been used and a copy of the completed document was maintained on the establishment file.

Roscommon County Council also uses the triplicate book of inspection reports, the template for which is provided in SOP M2: Hygiene Inspections of Establishments and SOP A6: Slaughter House Inspections / Audits. The audit team verified that the inspection report is completed for every official control inspection; however very little information is provided in written form about the non compliance. The audit team also confirmed, in the two establishments in which on-site verification audits were undertaken, that a copy of the report is left with the FBO. The audit team were advised that the non conformance report, provided as part of QP1 is not used.

4.6. Staff Performing Official Controls

Article 6 of Regulation (EC) No. 882/2204 requires that the competent authority shall ensure that all of its staff performing official controls receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner and that staff performing official controls keep up to date in their area of competence and receive regular additional training as necessary and have aptitude for multidisciplinary cooperation.

The veterinary services team in Roscommon County Council comprise one CVO, who is supported by five TVIs. Administrative support is also provided.

The local authority provided the audit team with a record of training undertaken and also noted that there would also be meetings, seminars, etc. which would be attended. The audit team also noted correspondence to the TVIs regarding new developments, amendments to the LAVS SOPS, etc. One such letter was verified by the audit team.

The local authority advised the audit team that there was an informal contingency plan in place with a neighbouring county.

4.7. Enforcement Activities

As part of the preparatory work for the audit, the use of enforcement actions under the FSAI Act, prosecutions and voluntary closures by Roscommon County Council were examined.

Since 2006, Roscommon County Council has taken three enforcement actions, under the FSAI Act. The audit team reviewed the files for two of these establishments. The third enforcement action, a closure order, related to an illegal slaughter which took place in the County. A prosecution in respect of this non compliance was recommended, but Roscommon County Council decided not to take a prosecution in this instance.

Table 2: Enforcement Action from January 2006 to June 2011

Enforcement Information	Numbers					
	2006	2007	2008	2009	2010	2011
Closure Order	0	0	0	0	1	0
Prohibition Order	0	0	0	0	0	0
Improvement Order	0	0	0	0	0	0
Prosecution	0	0	0	0	0	0
Improvement Notice	1	0	0	0	0	1
Compliance Notice (under SI 432/2009)	-	-	-	0	0	0

Information regarding enforcement activities is being supplied to the FSAI. As required, copies of all enforcement activity/notices have been sent to FSAI. It was noted by the audit team that the local authority had not counted any of these enforcement actions as a major non compliance, as part of the service contract schedule 4, monthly reporting activity.

4.8. Follow Up and Close Out of Non Compliances

Article 54 of Regulation (EC) No. 882/2004 requires that when the competent authority identifies non compliance, it shall ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non compliance and that operator's past record with regard to non compliance.

The establishment files relating to 12 food business operations were examined by the audit team. The audit team reviewed non compliances identified and the follow up carried out. Where enforcement action had been taken, the records relating to the inspection which gave rise to the enforcement action were examined, as well as the subsequent inspections, in which follow up of the non compliances identified were reviewed. It was noted that the last inspection outcome for 11 of the 12 establishments was satisfactory and the remaining 1 had an outcome of minor non compliance.

It was noted that where significant non compliances were identified, during official control inspections, follow up inspections took place. The audit team examined the records of such inspections and noted that recording of additional detail relating to the non compliances identified as well as the corrective actions, taken by the food business operators, should be maintained on subsequent inspection reports.

The requirements set out in the service contract between the FSAI and Roscommon County Council regarding the follow up & close out of non compliances identified during official control inspections are generally being complied with. Follow up & close out of non compliances are being carried out by the County Council within their functional area. However, the audit team noted that no major non compliances have been reported to the FSAI, as part of the service contract schedule 4, monthly reporting regime, although 3 enforcements have been taken under the FSAI Act since 2006. There was a discussion regarding the term 'major non compliances'. The local authority stated that it would perceive a major non compliance to be a situation in which there is grave and immediate danger to public health. It was agreed that there was no definition of the term and possibly this needed to be discussed by the FSAI & the LAVS.

4.9. Official Control Inspection Outcome

In line with the LAVS documented procedures for carrying out official control inspections (SOP A6: Slaughterhouse Inspection / Audits and SOP M2: Hygiene Inspections of Establishments) a record of the inspection is made on the relevant form. This includes a record of the inspection type and result as well as any observations or non compliances noted or corrective action required by the FBO.

There are three possible results for an inspection:

- Satisfactory
- Minor non compliance
- Unsatisfactory

Table 3: Inspections from January 2010 to June 2011³

Inspection Outcome	Number of Inspections	Percentage of Total Inspections
Satisfactory	131	81%
Minor non compliance	29	18%
Unsatisfactory	1	1%

³These are inspections carried out in the five approved establishments which were assessed as part of this audit.

It was noted that there were 35 inspections, for which the outcome had not been noted on the inspection report. During the audit, the local authority clarified what the outcome was for each of these inspections, and they have been included in the relevant inspection outcome category in Table 3, above.

During the review of the inspection outcomes, it was noted that there were 29 inspections in which an inspection result of minor non compliance was recorded. These 29 inspections related to 9 establishments. One of the records of the official control inspections, examined by the audit team, had an unsatisfactory result. A further surveillance inspection took place two weeks later, which had a satisfactory outcome. The audit team noted that the information relating to the non compliances identified as well as the corrective actions, taken by the food business operators, should be more detailed.

4.10. Reports to Food Business Operators

Article 9 of Regulation (EC) No. 882/2004 requires that the competent authority provide the FBO with a copy of the report on official controls carried out, at least in the case of non compliance.

The establishment files relating to 12 food business operations were examined by the audit team. The file relating to an establishment in which enforcement action was taken was reviewed. The records relating to the inspection which gave rise to the enforcement action were examined, as well as the subsequent inspections, in which follow up of the non compliances identified were reviewed. It was noted that the last inspection outcome for this establishment was satisfactory. The establishment files relating to 11 other FBOs were examined. The audit team reviewed non compliances identified and the follow up carried out.

It was noted that the last inspection outcome for 10 of these establishments was satisfactory, with an outcome of minor non compliance noted from the last inspection in the remaining establishment.

Records of official control inspections are maintained by the local authority. The audit team were advised that a copy of the inspection report, from the triplicate book, is left with the FBO after each inspection. The audit team noted that details recorded on the inspection reports in relation to non compliances were very brief. The audit team observed that these are official control records and noted that more detail in relation to the close out of non compliances by FBOs would be necessary to verify the enforcement of food law. The report relating to an inspection categorised as unsatisfactory was examined. The local authority elaborated that the inspection had been categorised as unsatisfactory due to unsatisfactory cleaning. The local authority carried out a surveillance inspection two weeks later and a note was recorded on the inspection report that the cleaning had improved. The audit team noted that recording of additional detail on the inspection reports would be beneficial.

The local authority advised the audit team that the non compliance and corrective action report, provided as part of QP1: Non Compliance Procedure, is not used.

5. FOOD BUSINESS OPERATOR CONTROLS PERFORMED IN ACCORDANCE WITH REGULATIONS 178/2002, 852/2004 & 853/2004 AND STATUTORY INSTRUMENT 432/2009

Two establishments were selected for on-site verification. The audit team selected establishments in which there were a number of non-compliances identified, in order to maximise the value of the on-site verification activity in the establishments. In each case, the official control inspection reports were assessed and the non-compliances identified were tracked through subsequent inspections to assess the follow-up action taken by the local authority.

The audit team were accompanied during the on-site verification visits. Although the focus was on the closure of non compliances raised during previous official control inspections, the audit was not restricted to these findings alone and recorded any non compliance(s) with food law identified on the day of the visits. The audit team provided a report of any findings where an FBO was not in compliance with food law to Roscommon County Council the following day to facilitate follow up by the local authority.

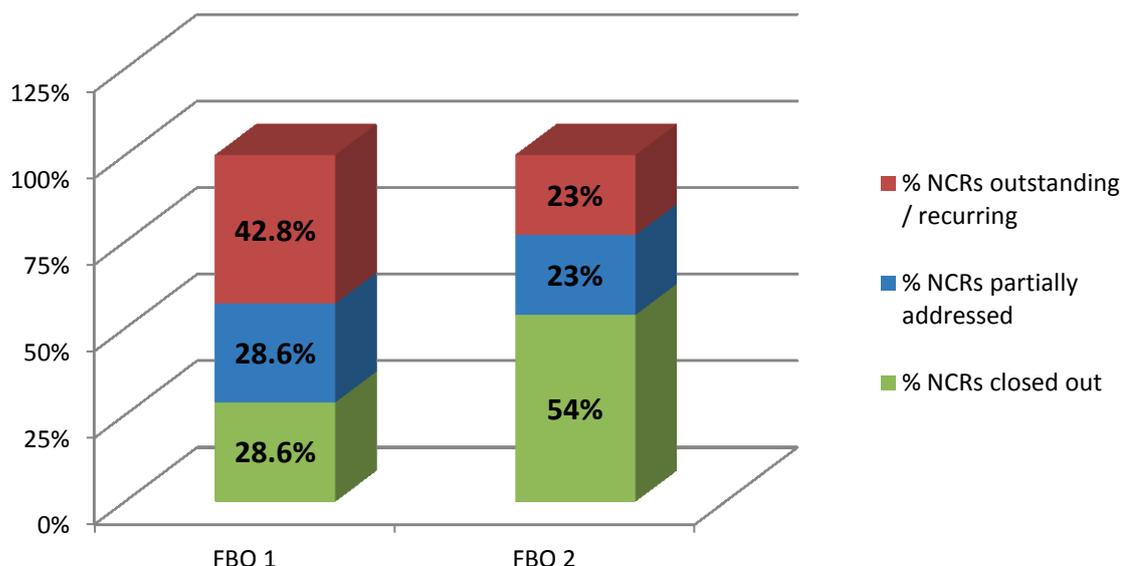
The numbers of non-compliances, which had been previously identified during official control inspections by the local authority, assessed in the two food businesses were seven and thirteen, respectively.

The audit team calculated the percentage of non-compliances in each of three categories:

- Closed out – that is, corrective action had been taken by the food business operator to comply with food law
- Outstanding/recurring – that is, corrective action had not been taken by the food business operator to comply with food law (outstanding) or corrective action had been taken, but the non-compliance had recurred
- Partially addressed – that is, corrective action had been taken by the food business operator, but it was insufficient or did not adequately address the non-compliance, and so further corrective action was required to comply with food law.

The results of the on-site verification activity in the two food business establishments are presented in Figure 2.

Figure 2: Status of Non Compliances



During the on-site verification activity, in the first food business establishment, the audit team verified that two of the seven non compliances had been addressed; remedial action in relation to two more had commenced but required further attention and three were outstanding or had recurred at the time of this audit.

In the second establishment, the audit team verified that seven of these non compliances had been addressed, remedial action had commenced in relation to three, but required further attention and three were outstanding or had recurred at the time of this audit.

Records and associated paperwork relating to the inspection of establishments were maintained in Roscommon County Council. Inspection reports, which included brief details of deficiencies identified, were left with the FBOs. The audit team noted that recording of additional detail on the inspection reports would be beneficial.

The audit team noted that official controls were generally being applied in a satisfactory manner in the two establishments audited. Records and associated paperwork relating to identification of non compliances during official control inspections were being maintained in Roscommon County Council.

The audit team were of the opinion that both establishments selected for on-site verification, as part of this audit, were operating, on the day of the audit, in line with the requirements of the approval for the establishment. In general, both establishments were operating at a standard required for an approved establishment. However, the audit team noted a number of non compliances which require corrective action, in the first establishment.

6. CONCLUSIONS

A review of inspection outcomes confirmed that when significant non compliances were identified during official control inspections, follow up action was taken, including enforcement action. The audit team noted that follow up in relation to non compliances, identified during official control inspections, was recorded, but that additional detail relating to the non compliances identified as well as the corrective actions, taken by the food business operators, should be maintained on subsequent inspection reports.

The audit team were of the opinion that both establishments selected for on-site verification, were operating, on the day of the audit, in line with the requirements of the approval for the establishment. In general, both establishments were operating at a standard required for an approved establishment. However, the audit team noted a number of non compliances which require corrective action, in the first establishment. The audit team noted that official controls were generally being applied in a satisfactory manner in the two establishments audited as part of the audit. However, it was noted that in the first establishment that 42.8% of the non compliances assessed by the audit team were outstanding or had recurred.

7. RECOMMENDATIONS

1. The local authority shall ensure that risk assessments are carried out in relation to all establishments in their functional area.
2. The local authority shall ensure that inspection type / outcome is always indicated on the completed report following an official control inspection.
3. The local authority shall record additional detail relating to the non compliances identified as well as the corrective actions, taken by the food business operators, on subsequent inspection reports.
4. Non compliances identified as part of the on-site verification activity should be closed out by the local authority in conjunction with the FBOs concerned.



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