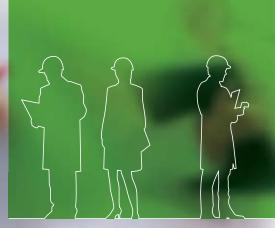


AUDIT REPORT

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

JUNE 2012



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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 Waterford 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 five establishment files were examined by the audit team. 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 Waterford County Council functional area, there are seven food establishments, which are supervised by the local authority veterinary service. Of these establishments; two are registered and five are approved, and it is these approved establishments that were included in this audit. 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 they were detailed and good records of the corrective actions taken by the food business operator were maintained.

Two establishments were selected for on-site verification. In the first establishment, the status of ten non compliances was assessed by the audit team. During the on-site verification activity, the audit team verified that six of these non compliances had been fully addressed and four had been improved but required further attention at the time of this audit.

In the second establishment, the audit team examined the status of 18 non compliances. The audit team confirmed that 12 of these 18 non compliances had been fully addressed, 3 had been improved but required further attention and 3 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, enforcement action was taken. The audit team noted that follow up in relation to non compliances identified during official control inspections, was well managed, with good records of corrective actions, taken by the food business operators 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 and, in general, at a standard required for an approved establishment. The audit team noted that official controls were being applied in a satisfactory manner in the two establishments audited as part of the audit.

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. Waterford County Council has entered into a service contract with the FSAI. The local authority, through the local authority veterinary service (LAVS), are 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 Waterford 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 Waterford 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)
- Waterford 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 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 Waterford 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 Waterford County Council. The purpose of the pre-audit questionnaire was to collate and confirm information regarding official controls and documented procedures within Waterford 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 Wednesday, June 15th & Thursday, June 16th 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 Waterford 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 five establishment files were examined by the audit team.

This evidence included:

- inspection reports for official control inspections,
- reports and warning letters to Food Business Operators (FBOs) in cases of deficiencies, and
- 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 Waterford County Council functional area, there are seven food establishments, which are supervised by the local authority. Two of these establishments are registered establishments, and so fall outside the scope of this audit. The audit team were provided with details of the inspection outcomes and records for official control inspections undertaken by the local authority for the five approved establishments. The FSAI holds a register of local authority supervised establishments and it was noted that all seven 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 by the local authority for each of the five establishments assessed as part of this audit. Official control inspections are unannounced, with the exception of annual audits and approval audits, which are pre-arranged with the FBO. A note is made on the inspection report when an official control inspection has not been unannounced, and this was verified by the audit team.

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 following enforcement action that several 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 verified that a risk assessment had been carried out in order to determine the nature and intensity of official controls, for the five approved establishments in Waterford County Council's functional area. Both establishments selected for on-site verification audits, had been categorised as medium risk.

The audit team noted that risk assessments had been updated, in light of a recommendation from a LAVS internal audit, which had taken place recently.

Table 1: Food Es	tablishments by Risk Category	
Risk Category	Number of establishments	
Very High	0	-
High	1	-
Medium	2	-
Low	2	-
Total	5	-

4.4. Frequency of Official Controls

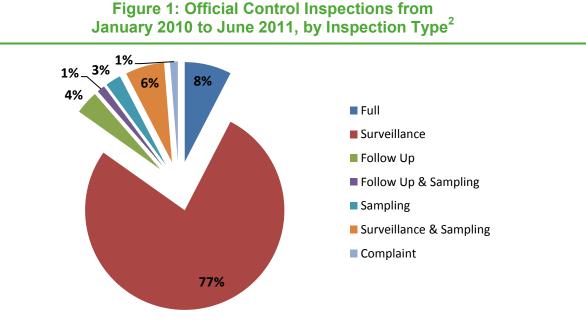
In Waterford County Council, the target for frequency of inspection is based on the results of the risk assessment for official controls.

As part of the audit, the audit team examined information in relation to the numbers and outcome of inspections which had taken place, in the five approved establishments assessed as part of this audit. A total of 79 official control inspections were carried out between January 2010 and June 2011, in the 5 establishments.

The audit team noted that there were ten inspection reports in which the inspection type had not been recorded. The audit team were advised that these would have been surveillance inspections.

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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 review of the inspection records for official control inspections following enforcement action, demonstrated that several follow up inspections were carried out, to ensure that the non compliances had been closed out effectively.

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.

 $^{^2}$ These are inspections carried out in the five approved establishments which were assessed as part of 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 Waterford 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 relation to the five 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.

Waterford 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. 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.

However, the audit team noted that non compliances are included on the food premises inspection report, which is left with the FBO, and that a good level of detail is provided as part of these reports.

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. 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 Waterford County Council comprise one CVO and two TVIs. Administrative support is also provided. There are also two deputies for the TVIs, who provide cover when the TVI is on holidays.

The local authority keeps a file of all meetings and training events attended. The audit team also noted correspondence to the TVIs regarding an upcoming course on HACCP, which the TVIs were being encouraged to attend. A note is also maintained on file regarding discussions / training undertaken with the TVIs, including keeping them updated on new and revised SOPs.

The local authority advised the audit team that there was an informal contingency plan in place with surrounding counties. Waterford County Council has developed an emergency contact list containing contact details for key personnel in the five surrounding counties³.

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 Waterford County Council were examined.

In 2010, Waterford County Council issued one enforcement action, under the FSAI Act, in relation to a food establishment.

³ **Update:** From 17th April 2012, Waterford County Council has a formal Section 85 agreement in place with two other local authorities in relation to statutory food safety functions. This means that the CVOs in each of the three local authorities would be legally empowered to act in food establishments in any of the three local authorities.

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

Table 2: Enforcement Action from January 2006 to June 2011

Information regarding enforcement activities is being supplied to the FSAI, as required. However, confirmation of compliance with an improvement notice by one FBO had not been notified to the FSAI. The audit team noted that good records of the follow up which took place with regard to this notice were maintained by the local authority in the establishment file. Additionally, it was noted that this enforcement notice was included as a major non compliance, as part of the service contract 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 five 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 four of these establishments was satisfactory and the remaining one 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 they were detailed and each non compliance was addressed individually in the report and correspondence to the FBO.

The requirements set out in the service contract between the FSAI and Waterford County Council regarding the follow up & close out of non compliances identified during official control inspections are being complied with. Follow up & close out of non compliances are being carried out by the County Council within their functional area.

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 in SMMPs) 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: Ins	pections from Jan	uary 2010 to	June 2011 ⁴
Inspection Outcome	Number of Inspections	Percentage of Total Inspections	
Satisfactory	66	8	3.5%
Minor non compliance	6	7.6%	7.6%
Unsatisfactory	0	0%	1.070
Outcome not noted	7	8.9%	8.9%

⁴These are inspections carried out in the five approved establishments which were assessed as part of this audit.

During the review of the inspection outcomes, it was noted that there were six inspections in which an inspection result of "minor non compliance" was recorded, which resulted in one improvement notice being issued. None of the records of the official control inspections, examined by the audit team, had an "unsatisfactory" result.

However, the audit team noted that on some inspection reports (seven) the inspection outcome had not been entered on the record.

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 case of non compliance.

The establishment files relating to five food business operations were examined by the audit team, including one in which enforcement action was 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 this establishment was satisfactory. The establishment files relating to four other establishments were examined. The audit team reviewed non compliances identified and the follow up carried out. It was noted that the last inspection outcome for this establishments. The outcome of minor non compliance noted from the last inspection in one establishment. The outcome for the last inspection in the remaining establishment was not noted.

Good 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. This was verified by the audit team in the two establishments in which on-site verification was undertaken.

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. Where non-compliances are detected that do not require the issuing of a legal notice, the food premises inspection report is used to detail the non compliances and the corrective action required. This is then given to the FBO instead of a separate non conformance report. The corrective actions by the FBO are then recorded on the subsequent inspection reports. The local authority advised the audit team that, at the end of each inspection, the outcome of the inspection is discussed with the FBO and they are required to sign the inspection report.

The audit team were advised that where there is ongoing good communication with the FBO and where the level of compliance is generally good, that the local authority does not issue a non-compliance and corrective action report, as it would be in addition to the routine inspection report.

Where the level of compliance falls below an acceptable level or the FBO repeatedly ignores written notice on the inspection report to take corrective action; then an enforcement notice would be issued.

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 Waterford County Council within five working days 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 ten and eighteen, 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.





During the on-site verification activity in the first food business establishment, the audit team verified that six of the ten non compliances assessed had been fully addressed and four had been improved, but required further attention at the time of this audit.

In the second establishment, the audit team confirmed that 12 of the 18 non compliances assessed had been fully addressed, 3 had been improved but required further attention and the remaining 3 non compliances were outstanding or had recurred at the time of this audit.

Records and associated paperwork relating to the inspection of establishments were well maintained in Waterford County Council. Inspection reports, which included details of deficiencies identified and corrective actions required were left with the FBOs.

The audit team noted that official controls were 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 well maintained in Waterford County Council.

The audit team noted inspection reports were left with the FBO, and the audit team verified this in both establishments audited as part of the on-site verification activity associated with this audit.

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 and, in general, at a standard required for an approved establishment.

6. CONCLUSIONS

A review of inspection outcomes confirmed that when significant non compliances were identified during official control inspections, enforcement action was taken. The audit team noted that follow up in relation to non compliances identified during official control inspections was well managed, with good records of corrective actions taken by the FBOs 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 and, in general, at a standard required for an approved establishment. The audit team noted that official controls were being applied in a satisfactory manner in the two establishments audited as part of the audit.

7. RECOMMENDATIONS

- 1. The local authority shall ensure that inspection type / outcome is always indicated on the completed report following an official control inspection.
- 2. 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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