

AUDIT
REPORT

Audit of Official Controls
carried out by the Local
Authority Veterinary Service
– Donegal County Council

NOVEMBER 2015



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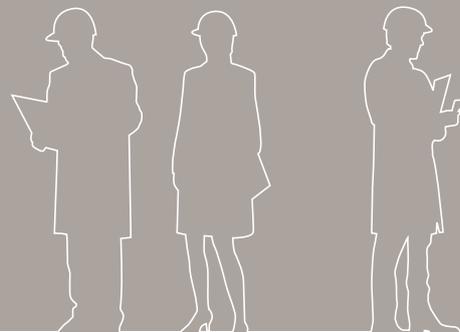


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1. GLOSSARY

CCP	Critical Control Point
FSAI	Food Safety Authority of Ireland
HACCP	Hazard Analysis Critical Control Point
OAPI	Official Agency Premises and Inspections database
SOP	Standard Operating Procedure

2. EXECUTIVE SUMMARY

This report describes the outcome of an audit carried out by the Food Safety Authority of Ireland (FSAI) in Donegal County Council from 20-21 November, 2014. The objective of this audit was to verify (i) the efficacy of official controls and (ii) compliance with official food control legislation and the agency's own procedures and plans.

Overall, the report concludes that official controls are in compliance with the legislation and there is an organised, structured and effective approach to the identification and follow-up of non-compliances in food businesses under the supervision of the veterinary service.

European hygiene legislation allows for the possibility of flexibility for small business through the development of guidance notes by industry subject to approval by the competent authorities and the European Commission. However, this flexibility clause has not been availed of to-date in Ireland and in the absence of national guidance, Donegal County Council developed its own system of flexibility for small businesses using HACCP-based principles. As an alternative to applying full HACCP in the premises, the business operators were using the generic documentation provided by the County Council which is based on the competent authority's opinion that the use of pre-requisite programmes is appropriate to ensure the reliable production of safe food.

The FSAI will need to review the appropriateness of this flexible approach nationally to ensure the consistent application of the rules in low throughput meat premises.

Donegal County Council has developed comprehensive food safety management systems for the establishments under their supervision. In one of the establishments audited, the food business operator was relying on the veterinary inspector to check the suitability of animals for slaughter and was not documenting his own checks on incoming animals. This may have resulted in food business operators becoming overly reliant on the council for managing food safety in their businesses and therefore, not fully understanding their own legal requirements as defined in food law.

Corrective actions to the findings of this report are required to ensure the on-going effectiveness of official controls and to enhance the consistency of the service in line with other local authorities. This is important to ensure that all food business operators under the supervision of a local authority veterinary service are subject to the same inspection process.

3. INTRODUCTION

3.1 Audit Objective

The FSAI is responsible for the enforcement of 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 FSAI. Donegal County Council has entered into a service contract with the FSAI and is responsible for the enforcement of food legislation as it applies to low throughput slaughterhouses, meat plants, cold stores and food vehicles (wholesaling meat) in the county. It is a requirement of the service contract and food legislation that the council ensures official controls are carried out regularly, on a risk-basis and with the 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. This audit was carried out for the purposes of assessing the effectiveness and appropriateness of the delivery of official controls by the council. Compliance by the veterinary staff with their responsibilities under relevant food legislation, adherence to the terms and requirements of the FSAI service contract, as well as conformance with relevant documented procedures, were assessed.

This audit was undertaken as part of the FSAI's audit programme for 2014. This report describes the audit objective, scope, methodology and the findings of the audit.

3.2 Audit Scope

The audit covered the organisation, planning, implementation and review of official controls within the council in order to confirm compliance with the requirements of the FSAI Service Contract, Regulation (EC) No 882/2004 and the Multi-Annual National Control Plan.

3.3 Audit Criteria and Reference Documents

The audit criteria referred to during the audit included the following:

- 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
- The FSAI Service Contract (including the FSAI Act)
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs, as amended
- Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs
- European Communities (Food and Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009) as amended
- 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
- The National Control Plan for Ireland 2012-2016
- Local authority hygiene plans and data supplied to the FSAI
- Local authority veterinary service documented procedures
- Local procedures

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. These procedures implement the FSAI audit obligations, defined in Schedule 5 of the service contract between the FSAI and Donegal County Council and in accordance with the requirements of Regulation (EC) No 882/2004 (including Article 6.1 of Commission Decision 2006/677/EC) and also the FSAI Act.

An evaluation plan describing the audit process and approach (including the scope, objectives, criteria and the audit team) was sent to the local authority ahead of the on-site activities. As part of the desktop element of this audit, a review of relevant information held within the FSAI was also carried out.

The audit included a review of the performance and delivery of official food controls by the county council. The audit team evaluated whether the official controls were being carried out in accordance with local authority veterinary service documented procedures which are used to implement the service contract requirements with the FSAI and related legislation.

As part of the audit of the food business operators, the audit team assessed the adequacy and performance of the controls put in place at establishment level. The implementation of good hygiene practices and principles of Hazard Analysis Critical Control Point (HACCP) as part of the food business operator's food safety management system and traceability systems, was assessed to determine if they were effective, adequately maintained and in compliance with food law.

On completion of the on-site visits to establishments, the audit findings relevant to each food business operator were outlined by the FSAI audit team. The food business operator was informed that the FSAI would communicate the audit findings to the county veterinary officer for follow-up. Following completion of the establishment audits, a final closing meeting was held by phone with the county veterinary officer, where findings were discussed.

4. AUDIT FINDINGS

4.1 Official Controls performed in accordance with Regulation (EC) No 882/2004

4.1.1 Organisation and Structure of Official Controls

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

Article 4(2)c The competent authorities shall ensure: that they have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively.

Findings

One full-time veterinary inspector carries out official controls in ten food establishments: six slaughterhouses, one full-time poultry establishment, one wholesaling premises that is also a seasonal poultry plant and two seasonal poultry establishments. Four temporary veterinary inspectors are contracted for ante-mortem and post-mortem duties. In the most recent temporary veterinary inspector contract, the potential for conflict of interest is addressed. However, it is not addressed in contracts with the other three temporary veterinary inspectors.

Laboratories used by the service are as indicated on the national residue control plan: Donegal County Council and Cork County Council.

A Section 86 Order is in place between Sligo County Council, Leitrim County Council and Donegal County Council to assist as agreed in the event of an incident or veterinary staff absences etc.

4.1.2 Coordination and Planning of Official Controls¹

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.

Article 4(5) of the Regulation requires that, when, within a competent authority more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Findings

The veterinary inspector has a system of planning and summarising the inspections carried out by completing an annual premises audit record which is held to the front of each establishment file. The audit record details the inspections to be carried out in each premises by quarter for the year. In addition, the veterinary inspector completes a monthly work schedule to ensure all monthly returns, audits, the Official Agency Premises Inspection database (OAPI) data etc. are completed. This allows the veterinary inspector to quickly review when each checklist was last completed and what inspections need to be completed by year end. All inspections are recorded on OAPI and on VETINSP (Donegal County Council Veterinary Access) databases, no later than the end of the month following the month the inspection was completed.

Standard Operating Procedure (SOP) No. D25 Risk Assessment of Establishments provides for the following inspection frequencies based on risk:

- Low-risk: 4-12 inspections per year
- Medium-risk: 6-24 inspections per year
- High-risk: 12–48 inspections per year
- Very high-risk: At discretion

The SOP allows for significant variation of inspection frequency (see discussion at 4.1.4).

¹**Recital 15** The competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented.

Recital 16 The competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient coordination between the central level and that regional or local level.

Microbiological samples are taken as per the instruction from Cork County Council, which manages a national sampling plan for all local authorities. Water samples are sent to Donegal County Council Laboratory. Annual water samples were taken in all establishments.

4.1.3 Registration/Approval of Establishments

Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments in accordance with the Regulation. In addition, it requires competent authorities to draw up and keep up-to-date, a list of food business operators which have been registered.

Article 2 of Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts states food business operators shall ensure that establishments producing sprouts are approved by the competent authority in accordance with Article 6 of Regulation (EC) No 852/2004. The competent authority shall approve those establishments only provided that they comply with the requirements set out in Annex I to Regulation (EC) No 852/2004 and in the Annex to this Regulation.

Findings

Premises were approved or registered as required by the Regulations.

4.1.4 Prioritisation of Official Controls and 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 food business operators, the reliability of own checks and any additional information on non-compliance.

Findings

Official controls are carried out regularly. Premises are risk assessed and the risk assessments for inspections and sampling are reviewed annually.

Frequencies of inspection in poultry plants depend on the number of days a year the businesses are open as they are seasonal. Inspection frequencies in the other slaughterhouses vary between 12 inspections per year to 25 inspections. In two establishments, the temporary veterinary inspector conducts a hygiene inspection/audit each time he carries out ante-mortem and post-mortem inspection and therefore, the frequency of surveillance audits is higher at those establishments (see Table 1).

In addition, desktop audits take place by the veterinary inspector to ensure all procedures and checklists have been completed and non-compliances are closed out.

Table 1: Number of Inspections by Risk Category

Risk Category	2012	2013
Low (Poultry)	4	5
Medium (Poultry)	2	1
Medium (Poultry)	1	10
Medium (Poultry)	1	1
Medium	45	50
Medium	85	62
Medium	18	12
Medium	12	14
Medium	24	21
Medium	23	25

Article 10 specifies how official controls should be carried out using appropriate control methods, such as monitoring, surveillance, verification inspection, audit, sampling and analysis. In Donegal, different techniques are used, e.g. full hygiene inspections, vehicle inspections, surveillance, sampling inspection etc.

In addition to checks on the hygiene conditions and an assessment of good manufacturing practice, good hygiene practice and HACCP-based procedures, Article 10 of Regulation (EC) No 882/2004 references a list of other factors that need to be included in an inspection such as raw materials, ingredients, packaging, cleaning, maintenance products, processes and labelling. There was evidence on the files of these processes and the non-hygiene legislation, e.g. labelling and food contact materials, being inspected.

4.1.5 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.

As per the service contract: *‘The official agency shall carry out official controls in accordance with documented procedures developed by agreement between the Authority and the Local Authority Veterinary Service. These procedures shall provide information and instructions for staff performing official controls’*

Findings

As per the service contract, the Local Authority Standardisation Working Group has put a series of documented procedures in place for local authority veterinary inspectors to ensure official controls are implemented in a standardised manner. The Donegal County Veterinary Officer is a member of the Standardisation Committee. In tandem with this national system, the veterinary officer has his own set of procedures to manage official controls within the agency.

Inspections are completed on the OAPI database and the county veterinary officer’s locally designed automated database which tracks all inspections and non-compliances. This system enables the veterinary officer to track non-compliances and produce summary reports.

The veterinary inspector completes the Food Premises Inspection Report and the audit reports as prescribed in the national procedures.

Nationally, there is no SOP in place dealing with how a local authority should verify the effectiveness of their activities, although locally, the veterinary inspector has a system in place for reviewing official controls.

4.1.6 Identification, 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.

Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed

Findings

The veterinary inspector has a documented system of checking previous non-compliances during the next inspection. This provides a documentary trail that non-compliances have been closed out.

4.1.7 Reports to Food Business Operators and Announcing Inspections

Article 9 of Regulation (EC) No 882/2004 requires that competent authorities draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned. The competent authority shall provide the food business operator with a copy of the report on official controls carried out, at least in case of non-compliance.

Article 3 (2) of Regulation (EC) No 882/2004 requires official controls to be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad-hoc basis.

Findings

A Food Premises Inspection Report as per SOP No. M2 Hygiene Inspections of Establishments, is left with the food business operator following an inspection. In addition, if a major non-compliance is identified, the Donegal County Veterinary Officer writes to the food business operator. In general, inspections are unannounced and audits are announced.

4.1.8 Verification and Review of Official Controls and Procedures

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

Article 4(6) of the Regulation requires the competent authorities to carry out internal audits or have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Article 8(3) states that the competent authorities must have procedures in place to verify the effectiveness of official controls and to ensure corrective action is taken when needed and to update documentation as appropriate.

Findings

A system of risk assessment for both establishment inspection and establishment sampling is in place and is reviewed.

An inspection programme is in place for each establishment and is reviewed regularly by the county veterinary officer. An annual internal audit programme for the temporary veterinary inspectors is in place. Close-out of non-compliances was well documented. An internal audit was carried out by the Sligo County Council Veterinary Inspector in February 2013 and follow-up has taken place.

There is no national SOP in place dealing with how local authority veterinary inspectors should verify the effectiveness of their activities.

Article 1 of Regulation (EC) No 882/2004 states that the performance of official controls shall be without prejudice to feed and food business operators' primary legal responsibility for ensuring feed and food safety, as laid down in Regulation (EC) No 178/2002.

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Following the on-site audits, the audit team noted that Donegal County Council has promoted a flexible approach to the application of HACCP-based procedures in approved premises under its supervision. The premises were using the generic documentation provided by the County Council, which is based on the competent authority's opinion that the use of pre-requisite programmes is appropriate to ensure the reliable production of safe food. European hygiene legislation allows for the possibility of this kind of flexibility in certain circumstances. However, this has not been availed of to-date in Ireland and therefore, in the absence of national guidance on flexibility, Donegal County Council developed this current system.

Donegal County Council Veterinary Service has developed food safety management systems for the establishments under their supervision. In one establishment audited, although a SOP was in place setting down the food business operator's obligation to accept only suitable animals for slaughter and presentation for ante-mortem inspection, in reality, the food business operator relied on completion of ante-mortem inspection by the official veterinarian to act as the record that the premises was in compliance with the requirements. In addition, the food business operator does not record the result of their final carcass inspection, as it is considered that completion of veterinary post-mortem inspection and application of the Health Mark would only happen when carcasses are visually clean. These practices undermine the food business operator's responsibility to accept and present only suitable animals for ante-mortem inspection and to produce visually clean carcasses to be presented for post-mortem inspection².

4.1.9 Staff Performing Official Controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure staff performing official controls are suitably qualified and experienced staff, that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

Findings

To retain their registration with the Veterinary Council of Ireland, the county veterinary officer and temporary veterinary inspectors are legally obliged to comply with the Council's Continuing Veterinary Education requirements.

There is no County Council food safety or official control training plan for the veterinary inspector, although the veterinary inspector documents his own training plan. The county veterinary officer attends national meetings and training provided by the FSAI and/or the Department of Agriculture, Food and the Marine (animal welfare).

Training is provided to temporary veterinary inspectors by issuing updates of the SOPs on a regular basis.

The county veterinary officer and one temporary veterinary inspector have been appointed as Designated Officers. Veterinary staff were authorised as required and warrants had been issued.

² The food business operator has now introduced a final inspection SOP that includes recording of the final inspection by the food business operator (25/11/2014).

4.2 Official Controls Performed in Food Establishments

An overview of the on-site verification work in both of the establishments audited is provided in Annex I of the report. A brief summary under (a) Structure, Maintenance and Operational Hygiene and (b) Food Safety Management System and (c) Traceability is provided below:

Findings

(a) Structure, Maintenance and Operational Hygiene

Article 4(2) of Regulation (EC) No 852/2004 establishes that the food business operator carrying out any stage of production, processing and distribution of food after the stage of primary production/associated operations shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, siting and size of food premises.

No significant hygiene or maintenance non-compliances were identified in the slaughterhouses audited.

(b) Food Safety Management System

On the basis of Article 5 of Regulation (EC) No 852/2004, the food business operator shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Regulation (EC) No 852/2004 allows the HACCP-based procedures to be implemented with flexibility so as to ensure that they can be applied in all situations.

In one establishment audited, the food business operator operated a food safety management system based on the implementation of pre-requisite programmes which had been developed by Donegal County Council. As a result, the food business operator did not identify the food safety hazards in the process and had not conducted a hazard analysis.

Reliance by the food business operator on competent authority controls to ensure the production of safe food, resulted in gaps in the implementation of the HACCP-based procedures and gaps in traceability records indicate a requirement for training of the food business operator.

(c) Traceability

Traceability requirements were being complied with in the one slaughterhouse audited. In the other slaughterhouse, a system of traceability was in place. However, the traceability records prescribed in the food safety management system were not fully completed.

5. CONCLUSIONS

Donegal County Council supervises ten food establishments under service contract to the FSAI. The audit team confirmed that there was a well-organised, structured and effective approach for the delivery of official controls. The council has applied flexibility to the application of HACCP in the premises under its supervision. The FSAI will need to review the appropriateness of this approach nationally to ensure the consistent application of the rules in low throughput meat premises.

Establishments are inspected regularly and non-compliances are systematically identified and closed out.

6. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION

Audit findings requiring corrective action are listed in the corrective action plan. The findings identified during this audit should be addressed by Donegal County Council so that the effectiveness of the service can be improved. In addition, findings in this series of audits should be disseminated to all local authorities by the local authority veterinary service and/or the FSAI to enhance official controls nationally.

Annex I: Summary of On-site Findings

Food Business Operator 1

The slaughterhouse was not in operation on the day of the audit. Hygiene and maintenance at the premises were satisfactory.

Findings related to non-compliance with Food Law	
1.	<p>HACCP-based Procedures</p> <p>Regulation (EC) No 852/2004, Article 5(1) <i>Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.</i></p> <p>Regulation (EC) No 852/2004, Article 5(2)</p> <ul style="list-style-type: none"> (a) <i>Food business operators shall identify any hazards that must be prevented, eliminated or reduced to acceptable levels</i> (b) <i>identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels</i> (c) <i>establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards</i> (d) <i>establishing and implementing effective monitoring procedures at critical control points</i> (e) <i>establishing corrective actions when monitoring indicates that a critical control point is not under control</i> (f) <i>establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and</i> (g) <i>establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f)</i> <p>Regulation (EC) No 853/2004 Annex II SECTION II: OBJECTIVES OF HACCP-BASED PROCEDURES <i>Food business operators operating slaughterhouses must ensure that the procedures that they have put in place in accordance with the general requirements of Article 5 of Regulation (EC) No 852/2004 meet the requirements that the hazard analysis shows to be necessary and the specific requirements listed in point 2.</i></p> <p>The food business operator operated a food safety management system based on the implementation of pre-requisite programmes which had been developed by Donegal County Council. As a result, the food business operator did not identify the food safety hazards in the process and had not conducted a hazard analysis.</p> <p>The SOP for recording chill temperatures was not in line with the check sheet. The chill temperature was an average reading of two temperatures on a digital display³. The veterinary inspector calibrates the data logger for the chills.</p> <p>The food business operator uses the ante-mortem/post-mortem certificate as his record that the final carcass check has been done and is satisfactory. The food business does not document this as a control but uses the veterinary inspector's post-mortem check as sign-off for the carcass. The food</p>

³ The food business operator's SOP has been adjusted so that both temperatures are now recorded (25/11/2014).

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	<p>safety management system states the failures can be recorded but there was no evidence of this⁴.</p> <p>There were gaps in the records kept by the food business operator that were outlined in the food safety management system, e.g. pest control.</p>
2.	<p>Staff Training</p> <p>Regulation (EC) No 852/2004, Annex II, Chapter XII (2) <i>Food business operators are to ensure that those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles</i></p> <p>Reliance on competent authority controls to ensure the production of safe food, gaps in the implementation of the HACCP-based procedures and gaps in traceability records indicate a requirement for training for the food business operator.</p>
3.	<p>Traceability</p> <p>Regulation (EC) No 178/2002, Article 18</p> <ol style="list-style-type: none"> 1. <i>The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be incorporated into a food or feed shall be established at all stages of production, processing and distribution.</i> 2. <i>Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.</i> 3. <i>Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.</i> 4. <i>Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions. No traceability system in place to identify where food is purchased.</i> <p>Of the products reviewed, there was a system of traceability in place. However, the traceability records were not available for a number of batches identified by the audit team⁵.</p>

⁴ The food business operator has now introduced a final inspection SOP that includes recording of the final inspection by the food business operator (25/11/2014).

⁵ All required documentation was available in the premises at the time of the audit but was not readily retrievable. The food business operator has now instigated a new filing system to aid the recovery of documentation in a timely manner (25/11/2014).

Food Business Operator 2

The slaughterhouse was not in operation on the day of the audit.

Hygiene and maintenance at the premises were satisfactory.

Documentation was reviewed and compliant for food safety management system and traceability requirements.



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