

AUDIT REPORT

Audit of Official Controls in Department of Agriculture, Food and the Marine supervised 'Ready-to-eat' and 'Ready-to-heat' Meat Establishments



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SEPTEMBER 2016

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1. GLOSSARY

DAFM	Department of Agriculture, Food and the Marine
FSAI	Food Safety Authority of Ireland
НАССР	Hazard Analysis and Critical Control Point
SOP	Standard Operating Procedure
VPN	Veterinary Procedural Notice

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2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) 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 FSAI is required to verify that the system of official controls is working effectively. For the purposes of assessing the delivery of official controls in the official agencies, the FSAI conducts an annual programme of audits.

The FSAI completed an audit of the food safety official controls performed in food manufacturing establishments by the Veterinary Public Health Inspection Service of the Department of Agriculture, Food and Marine (DAFM). The audit was undertaken as part of the planned programme of audits carried out by the FSAI in 2015-2016 to determine the level of compliance with European legislation and conformance with the service contract in place between DAFM and the FSAI.

The audit was carried out in three regions of the six Veterinary Public Health Inspection Service operational regions. The first part of the audit involved an examination of official control files and inspection reports. The second part involved an on-site verification audit of six food manufacturing establishments, classified as 'ready-to-eat'.

Overall, the audit concluded that the official controls carried out by the Veterinary Public Health Inspection Service in respect of 'ready-to-eat' manufacturing establishments are in compliance with the legislation and there is an organised approach to the identification and follow-up of non-compliances. Establishments cooking meat products are not differentiated in the risk assessment process regardless of whether they are producing 'ready-to-eat' and or 'ready-to-heat' products. 'Ready-to-eat' establishments are not identified separately on the list of approved premises, which would allow a more precise evaluation of the risk associated with these premises, and the allocation of resources accordingly. The audit identified training needs for inspectors and a need for more streamlined documented procedures. Access to establishments was slow which could potentially impede the effectiveness of unannounced inspections by inspectors.

In the six food establishments audited, non-compliances identified by the audit team had not been identified during previous veterinary audits in relation to the HACCP (hazard analysis and critical control point) requirements (Regulation (EC) No 852/2004) and the requirements of Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, in particular shelf-life.

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. DAFM has entered into a service contract with the FSAI and is responsible for enforcing food legislation in large scale meat and milk food manufacturers in Ireland as well as other official control activities. It is a requirement of the service contract and food legislation, that DAFM 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 systems of official controls put in place by the official agencies are working effectively. This audit was carried out to assess the effectiveness and appropriateness of the delivery of official controls by the Veterinary Public Health Inspection System in 'ready-to-eat' meat and 'ready-to-heat' manufacturing establishments. Compliance by the Veterinary Public Health Inspection Service with relevant official controls legislation, adherence to the terms and requirements of the FSAI service contract, as well as conformance with relevant documented procedures, was assessed. The audit was carried out at Veterinary Public Health Inspection Service regions and in six food manufacturing establishments.

This audit was undertaken as part of the FSAI's audit programme for 2015-2016.

3.2. Audit Scope

The audit covered the organisation, planning, implementation and review of official controls within the Veterinary Public Health Inspection Service of DAFM at national and regional levels in order to confirm compliance with the requirements of the FSAI Service Contract, Regulation (EC) No 882/2004, the National Control Plan for Ireland 2012-2016 and DAFM's own documented procedures, mainly Veterinary Procedural Notices (VPNs) and Standard Operating Procedures (SOPs). As part of this audit, compliance with food law in the selected food manufacturing establishments was also assessed.

3.3. Audit Criteria and Reference Documents

The audit criteria referred to during the audit included:

Principal audit criteria

- FSAI Service Contract Including relevant legislation specified in Schedule 1 Service Contract DAFM
- Food Safety Authority of Ireland Act, 1998 (S.I. No. 29 of 1998), as amended
- <u>Regulation (EC) No 882/2004</u> on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- <u>Regulation (EC) No 852/2004</u> on the hygiene of foodstuffs, as amended
- Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, as amended
- <u>Regulation (EC) No 2073/2005</u> on microbiological criteria for foodstuffs, as amended
- <u>Regulation (EU) No 1169/2011</u> on the provision of food information to consumers

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- <u>Regulation (EC) No 882/2004</u> on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- <u>Commission Decision 677/2006</u> setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004

Secondary criteria

- <u>Regulation (EC) No 178/2002</u> 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
- <u>The National Control Plan for Ireland 2012 2016</u>
- Service plans and data supplied to the FSAI
- Documented Procedures; VPNs and SOPs
- Guidance Notes/Codes of Practice
- Other relevant legislation detailed in the FSAI/DAFM Service Contract

3.4. Audit Methodology

This audit of official controls was undertaken using the audit procedures documented in the FSAI's Quality Management System. These procedures implement the FSAI's audit obligations, defined in Schedule 5 of the service contract between the FSAI and DAFM, and in accordance with the requirements of Regulation (EC) No 882/2004, Commission Decision 2006/677/EC, and Section 48(9) of the Food Safety Authority of Ireland Act, 1998 as amended.

Before the audit, an evaluation plan describing the audit process and approach (including the scope, objectives, criteria and the audit team) was sent to DAFM. The audit started with an opening meeting with the Veterinary Public Health Inspection Service and the Meat Policy Division. The audit team looked for evidence at a national level as to how the service consistently and effectively implements Regulation (EC) No 882/2004, delivers its obligations under the service contract, and adheres to documented procedures. The audit also looked for evidence to confirm how this is monitored and reviewed at regional level.

The auditors met with the regional superintending veterinary inspector in each of the three regions to review documented procedures and also the files and inspection reports for 'ready-to-eat' and 'ready-to-heat' meat manufacturing establishments supervised by Veterinary Public Health Inspection Service in that region.

The audit team then visited manufacturing establishments in each region, accompanied by the relevant veterinary inspector, to assess the adequacy and performance of the official controls put in place at establishment level and to assess the compliance with food law by the food business operator.

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. A final closing meeting was held with the national office and the three regions where all 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.

Findings

The Veterinary Public Health Inspection Service provides a range of food safety/food control services in accordance with the service contract between the FSAI and DAFM. These services include inspection of food businesses and food sampling to ensure compliance with food legislation, the management of food incidents and a range of compliance building/education measures for food businesses. The Veterinary Public Health Inspection Service operates regionally under the supervision of a regional superintending veterinary inspector. The regional superintending veterinary inspector organises the inspection of food establishments in their local region.

The Veterinary Public Health Inspection Service is organised into six regions and is staffed by veterinary and technical staff. In 2015, there were 54 veterinary inspectors and six superintending veterinary inspectors allocated to the Veterinary Public Health Inspection Service nationally. However, at the time of the audit, eight veterinary inspector vacancies existed. Contract veterinary inspectors referred to as locum tenens have been recruited on a contract basis to replace veterinary inspectors but their training and duties are more restrictive than permanent veterinary inspectors. Technical staff (five district superintendents, 58 senior agricultural officers and 102 technical agricultural officers) support the supervision and regulatory work carried out by veterinary inspectors in food establishments. Since the public sector recruitment embargo, there has been a depletion of technical staff in all six Veterinary Public Health Inspection Service regions with no replacements and significant numbers of vacancies now exist which is causing difficulties at plant level for DAFM to deliver all of the required services.

The organisation of official controls in food manufacturing establishments is guided in the main by the SOP "*Food* Safety Management System 006/2008 rev03 (06/14)" (for establishment attached to slaughterhouses) and SOP "17/2012 Audits and Inspections of Food Business Operators Food Safety Management Systems (veterinary inspector AP") (for stand-alone food manufacturers).

4.1.2. Coordination and Planning

Article 4(3) of Regulation (EC) No 882/2004 states when a Member State confers the competence to carry out official controls on an authority or authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection. 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.

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Findings

In each region, official controls are organised and planned on the basis of risk. Inspections are planned in order to meet the requirements of SOPs and risk assessments are performed for all establishments following an audit. Routine sampling is planned in accordance with the veterinary laboratories and the annual microbiological and chemical residue sampling plans.

Due in the main to staff shortages and the recruitment of new veterinary inspectors that are not yet experienced in carrying out audits, a number of audit targets for ready-to-eat establishments were not met in one of the three regions audited in 2015. Facilities and equipment are in place locally for staff to carry out their work and legal powers and authorisations were in place. Coordination within regions is arranged effectively by regional superintending veterinary inspectors and the evidence of meetings and cooperation on inspections was seen on files.

The Veterinary Public Health Inspection Service has national meetings to discuss and organise training, sampling and the introduction of new legislation.

There is communication between the veterinary inspectors in the establishment, the regions and central level regarding targets and inspection numbers via PAIRs (Pre-audit Inspection Checks and Records) documents. These are completed locally by the veterinary inspectors and collated by the district superintendent from the technical staff before being forwarded to the meat policy division for collation of returns nationally. They are not used locally or in the region to monitor targets.

4.1.3. Registration and Approval

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration of food and feed business establishments. Article 6 (2) of Regulation (EC) No 852/2004 requires every food business operator to notify the appropriate competent authority with a view to the registration of each establishment.

Article 3 of regulation 854 requires the approval of establishments if certain activities are taking place on food of animal origin such as mincing, cooking etc. The competent authority shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it meets the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 and other relevant requirements of food law.

Findings

In the files reviewed, all food manufacturing establishments were approved under Regulation (EC) No 853/2004 as required. In one region, two establishments operated by the same food business operator but located in two separate sites, had one approval number which is inconsistent with other approvals. One establishment had two approval certificates (one issued by DAFM and one by the Sea-Fisheries Protection Authority).

Food business operators are formally approved as 'meat product' establishments and the 'ready-to-eat' status is not included on approval certificates. For operational purposes, these establishments are also classified by DAFM as 'ready-to-eat' food manufacturers because they cook products. However, in two of the establishments, the product labels contained full cooking instructions and there was ambiguity as whether these food business operators produced 'ready-to-eat' or 'ready-to-heat' foods. The status of these establishments has implications for developing their procedures based on HACCP principles, sampling requirements and official control risk assessments.

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 operator compliance, the reliability of own checks and any additional information on non-compliance. Controls shall in general, be carried out without prior warning.

Findings

Inspections

Risk-based priorities for official controls are planned in order to meet the requirements of SOP 17 and SOP 6 which results in at least two audits to be scheduled per year in 'ready-to-eat' manufacturing establishments. These audits are carried out by veterinary inspectors in stand-alone establishments under SOP 17 and by the regional superintending veterinary inspector in establishments attached to slaughterhouses under SOP 6. All food businesses were risk profiled following audits and an annual schedule of audits is compiled by the regional superintending veterinary inspector. Inspection frequencies were scheduled between a minimum of two inspections and maximum of four inspections, but in reality the number of inspections exceeded the SOP requirement (inspections can be limited to sampling, export certification, checking one or two items on inspection checklist). Establishments cooking meat products are not differentiated in the risk assessment process regardless of whether they are producing 'ready-to-eat' and or 'ready-to-heat' products. 'Ready-to-eat' establishments are not identified separately on the list of approved premises, which would allow there to be a more precise evaluation of the risk associated with these premises, and the allocation of resources accordingly.

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 performing official controls.

Findings

The Veterinary Public Health Inspection Service has a significant number of procedures and templates in place for veterinary inspector s to complete when carrying out official controls. In 2016, SOPs, VPNs and forms are being reviewed on E-zone at national level to eliminate duplications and identify gaps in procedures. A SOP outlining the labelling requirements under the new Food Information to Consumers (FIC) Regulations was being trialled but was not in place at the time of the audit.

The Annex 3 veterinary inspector AP form under SOP 17 (Report on food safety management system audit carried out by DAFM Veterinary Public Health Inspection Service in order to evaluate the food business operators food safety management system) had been used by veterinary inspectors during inspections in all of establishment audited as part of this audit. There is however, duplication with how this form and other forms are used, e.g. HACCP Pre-requisites (HPRs), CCP1 rev 01 (0164) was also used. This resulted in some forms being used for official controls in some establishments but not in others.

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Documented procedures with forms for completion are in place for microbiological and labelling inspections. The prescribed forms were not always used, e.g. the audit form for veterinary inspector checks with Regulation (EC) No 2073 (Annex I form) was not seen in all establishments audited. In one of the establishments audited, the veterinary inspector completes the SOP6 FSMS Rev 2 (05 14) HPRS form when conducting microbiological inspections. In addition, although labelling checks were carried out, the labelling check sheets were completed in two of the six establishments audited.

The general responsibilities and activities of regional superintending veterinary inspectors are described in their role profile, but there is no national guidance for regional superintending veterinary inspector s on how to conduct reviews of the effectiveness of official controls. During 2015, regional superintending veterinary inspectors introduced standardised forms to be completed when carrying out supervisory checks on veterinary inspectors. At the time of the audit, these were not being fully used and different forms across the three regions were used by regional superintending veterinary inspectors when carrying out supervisory and audit activities whilst some conducted on-site supervisory audits, others did desk-based reviews.

The role of the senior agricultural officer and the technical agricultural officer is organised locally by the district superintendent and the regional superintending veterinary inspector. It is not documented in SOP 17 how the outcome of the inspections by technical staff is used by the veterinary inspectors when carrying out official controls in meat plants.

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 noncompliance, 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

In general, non-compliances are identified by veterinary inspectors and follow-up to non-compliances was well documented on file.

In the six food establishments audited, some of the non-compliances in relation to the operation of high-care areas, HACCP, critical limits and validation of critical control points, shelf-life determination and Regulation (EC) No 2073/2005 identified by the audit team that had not been previously identified by official controls.

4.1.7. Reports to Food Business Operators

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

In all cases where non-compliances were identified, reports were forwarded to food business operators after official control inspections or audits. In general, the reports were well documented and issued in a timely manner.

4.1.8. Verification and Review of Official Controls

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

Regional Veterinary Public Health Inspection Service meetings take place where official controls are discussed amongst the veterinary inspectors and the regional superintending veterinary inspector. There is a review of veterinary inspector inspections and files and the regional superintending veterinary inspectors are familiar with issues in establishments locally. The new '*Veterinary Inspector Audit of Veterinary Controls and Records*' checklists are comprehensive checklists which will enable the regional superintending veterinary inspector to carry out a full review of official controls carried out by veterinary inspectors in each food business operator. These forms will facilitate the review of the effectiveness of official controls at local level but at the time of audit, these forms were relatively new and had not been applied to all establishments. They are not part of the national SOPs and VPNs system.

Different systems to verify the effectiveness of official controls were in place in each region. In each of the regions audited, the regional superintending veterinary inspector had conducted desk-based audits or on-site supervisory audits to verify that official controls were being carried out consistently and in line with SOPs. Joint inspections also take place where regional superintending veterinary inspectors accompany veterinary inspectors on difficult inspections, approval inspection, etc. Evidence of these joint inspections was seen on the files reviewed. Different forms were used to document these supervisory audits.

Delayed access to food business operator premises may have implications for the effectiveness of unannounced official controls.

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

Training in local areas is dependent on a national training plan which is developed annually. Staff interviewed during the audit were knowledgeable of the requirements of the national and EU legislation requirements and also with the DAFM documented procedures.

The non-compliances identified by the audit team in food businesses highlighted a need for further training for veterinary inspectors on the validation of critical control points (CCPs), establishing critical limits in food safety management systems, on the application of Regulation (EC) No 2073/2005 and in particular, shelf-life.

Service Contract Requirements

Findings

Review of the files showed that there are limited levels of official controls being carried out or documented on nonhygiene legislation covered in the service contract unless a national programme is in place, e.g. food contact materials, additives.

4.2. Food Business Operator Findings

The audit team provided a report to each region of the findings identified in the food manufacturing establishments audited.

4.3. Audit Findings ~ Region 1 East

Offic	ial Control Audit Findings
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) requires that the competent authorities ensure that: they have, or have access to, an adequate laboratory capacity for testing a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively appropriate and properly maintained equipment and facilities legal powers to carry out official controls
	A structured approach to the organisation of staff for the performance of official controls was in place within the East region. The region is responsible for carrying out official controls in 42 approved food establishments of which five are classified as 'ready-to-eat' meat establishments.
	The current staff complement in the East region for food control is one superintending veterinary inspector, 11 veterinary inspectors (including two local tenens and one veterinary inspector is on long-term maternity leave which has not been replaced), one district superintendent, 14 senior agricultural officers and 13 technical agricultural officers. The veterinary inspector allocation for the region is 12.
	Responsibilities for delivery of the food control service is organised by the regional superintending veterinary inspector.
	Sampling and testing programmes are organised centrally by the relevant DAFM laboratories.
	Veterinary inspectors were authorised centrally as required and warrants had been issued.
2.	Coordination and Planning
	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.
	Risk-based priorities for official controls within the East region in 2015, are planned/scheduled in order to meet the requirements of SOP 17 ('ready-to-eat' plants) in the case of audits and inspections. They are also in accordance with the national microbiological and chemical analysis sampling plans devised by the laboratories.
	In 2014, two of the five and in 2015, three of the five 'ready-to-eat' establishments were not inspected in line with the rate of inspection required under SOP 17.

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erintendir veterinary regional s	chedules and review dit and corrective a n standalone premis g veterinary inspection nal superintending v inspectors to head uperintending veter	v audits in standa ction reports. Or ses in conjunctior tor carries out au veterinary inspec dquarters using a inary inspector is ector, this is the r	s outlined SOP 17. The lone establishments. The occasion, the regional in with the supervisory ver- dits and pre-operative of tor inspected/audited al PAIRS (Pre-audit Inspections tar esponsibility of the vete the target.	This includes superintendin eterinary thecks in all I five 'ready-to ection Checks rgets are not
	nented procedures		horities carry out their rmation and instructio	
i		th documented procedures edures up-to-date.		th documented procedures containing information and instruction edures up-to-date.

¹ Risk Rating Score 12-14 (2 audits and 2 unannounced inspections), Risk Rating Score 15-17 (2 audits and 3 unannounced inspections) and Risk Rating Score >/18 (2 audits and 4 unannounced inspections)

	The audit team verified that in the East region, inspections are planned in accordance with SOP 17 and veterinary inspectors complete the Annex 3 form.
	Supervision of the veterinary inspectors and official controls by the regional superintending veterinary inspector are not documented nationally in a SOP but are discussed by the regional superintending veterinary inspectors and forms have been agreed. Different forms are used by the regional superintending veterinary inspector when conducting his official controls, e.g. Senior Veterinary Inspector Audit Form, MS word report of the inspection and Veterinary Inspector Audit of Veterinary Controls and records. Other records, e.g. Senior Veterinary Inspector Audit of Veterinary Inspector Audit of Veterinary Inspector Senior Veterinary Inspector Audit of Veterinary Inspector Senior Veterinary Inspector Senior Veterinary Inspector Audit of Veterinary Inspector Senior Veterinary In
	In one establishment, risk assessments were performed when there was no veterinary inspector AP audit conducted.
5	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.
	Non-compliances identified during manufacturer's inspections are recorded by the veterinary inspector on a corrective action report and are followed up by the veterinary inspectors and this was verified by the auditors.
	Findings from previous inspections are assessed for their close-out at the next inspection and this was well documented on visit records.
	Onsite verification was carried out in three establishments.
	Establishment 1
	Two Senior Veterinary Inspector Audits and a Veterinary Inspector AP Audit had taken place in this establishment in 2015. A Compliance Notice was issued in July 2015 regarding cleaning and maintenance of the mincer. Issues around the cooking CCP, shelf-life and staff training were not identified during the Official Control Veterinary Inspector AP audit. An official control finding requesting the food business operator to get the cooker externally validated was identified in 2014 but had not been closed out by the food business operator. Cleaning non-compliances identified in the 2014 Veterinary Inspector AP report and in a Senior Veterinary Inspector Audit in 2015, continue to be an issue for this plant.
	Establishment 2
	Two Senior Veterinary Inspector Audits and a Veterinary Inspector AP Audit had taken place in this establishment in 2015. A Compliance Notice was issued in July 2015 regarding HACCP and product flow and significant improvements have been made to the HACCP documentation and food business operator controls onsite. Issues with shelf-life are the cause of a significant number of complaints and official controls had not identified this.
	Establishment 3
	Two Senior Veterinary Inspector Audits and a Veterinary Inspector AP Audit have taken place in this establishment in 2015. A Compliance Notice was issued in July 2016 for tempering product in a nearby cold store. Issues around the validation of the cooking, CCP, and the maintenance of the freezer were not identified at official controls audits.

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6	Reports to Food Business Operators
	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.
	The SOP 17 requires audit and inspection reports to be issued following an audit. From the files reviewed, food business operators received a written report in all cases.
7	Verification and Review of Official Controls and Procedures
	Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls
	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.
	Performance monitoring, i.e. the achievement of audit targets against the plan, and a review of official controls are carried out by the regional superintending veterinary inspector within the east region.
	The regional superintending veterinary inspector carries out pre-operative checks in all slaughterhouses annually and in a number of stand lone meat establishments.
	Evidence of joint inspections by the veterinary inspector and the regional superintending veterinary inspector was also seen on the files within the region where an issue arises or a change to the approval is required.
	The regional superintending veterinary inspector logs all non-compliances report identified during official controls to monitor and ensure close-out.
	As well as individual one to one meetings with veterinary inspectors, two annual regional meetings take place where official controls and documented procedures are discussed by the regional superintending veterinary inspector and the veterinary inspectors.
	The completion of check sheets by veterinary inspectors as listed in SOPs, e.g. microbiological; traceability check sheet is not documented by the regional superintending veterinary inspector during the audits.

8	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.
	Training is dependent on a national training plan which is developed annually. Staff interviewed during the audit were knowledgeable of the requirements of the national and EU legislation requirements and also with the DAFM documented procedures.
9	Coordination and Communication
	Recital 16 of Reg. 882/2004 requires competent authorities to 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.
	Art.4.5 of Reg. 882/2004 states 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.
	There is communication between national management, the regional superintending veterinary inspector and the local team regarding targets and inspection numbers.
	Coordination of official controls within the east region office and updates on official control activities is provided via regional and national staff meetings. The audit team was provided with agendas and examples of meetings that had taken place, demonstrating that information was being communicated and disseminated to staff in the region.
10	Registration and Approval
	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 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 3 of regulation 854/ 2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation 882. In addition Article 3(3) states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.
	The manufacturer's establishment files reviewed were approved as required under Regulation (EC) No 853/2004.

4.4. Audit Findings ~ Region 2 North East

Officia	al Control Audit Findings
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) requires that the competent authorities ensure that: they have, or have access to, an adequate laboratory capacity for testing a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively
	 appropriate and properly maintained equipment and facilities legal powers to carry out official controls
	A structured approach to the organisation of staff for the performance of official controls was in place within the North East region. The office is responsible for carrying out official controls in 42 approved food business operations of which ten (nine standalone meat plants and one attached to a slaughterhouse) are classified as 'ready-to-eat' meat establishments.
	The current staff complement in the North East office for food control is one superintending veterinary inspector, nine veterinary inspectors, one district superintendent, 14 agricultural officers and 13 technical agricultural officers.
	Responsibilities for delivery of the food control service is organised by the regional senior veterinary inspector.
	Sampling and testing programmes are organised centrally by the relevant DAFM laboratories.
	Veterinary inspectors were authorised centrally as required, and warrants had been issued.
2.	Coordination and Planning
	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.
	Risk-based priorities for official controls within the North East office in 2015 are planned/scheduled in order to meet the requirements of SOP 17 ('ready-to-eat' plants) and SOP 6 (slaughter plants or 'ready-to-eat' plants attached to slaughter plants) in the case of inspections and in accordance with the national microbiological & chemical analysis sampling plans devised by the laboratories.
	It was evident from the file review that in 2014, not all 'ready-to-eat' manufacturers were audited in line with the frequency of audits for the relevant risk category however, targets were met in 2015.

	Column1	Risk Rating ²	Required Audits	Audits carried out 2015			
	Food business operator 1	15	2	2			
	Food business operator 2	15	2	2			
	Food business operator 3	18	2	2			
	Food business operator 4	15	2	2			
	Food business operator 5	15	2	2			
	Food business operator 6	18	2	2			
	Food business operator 7	18	2	2			
	Food business operator 8	18	2	2			
	Food business operator 9 (Attached to slaughter) (regional superintending veterinary inspector visits)	17	2	2			
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.							
Routine audit and inspection targets are set following a risk assessment as outlined in SOP 6 and SOP 17. The regional superintending veterinary inspector carries out SOP 6 audits in premises attached to slaughterhouses. The regional superintending veterinary inspector schedules and reviews audits in standalone establishments. This includes being copied on risk assessments, audit and corrective action reports. On occasion, the regional superintending veterinary inspector conducts audits in standalone premises in conjunction with the supervisory veterinary inspector.							
regional s	s are reported by veterinan uperintending veterinary ins uperintending veterinary ins	spector is copied.	Inspections targ	ets are not monitored	by the		

² Risk Rating Score 12-14 (2 audits and 2 unannounced inspections), Risk Rating Score 15-17 (2 audits and 3 unannounced inspections) and Risk Rating Score >/18 (2 audits and 4 unannounced inspections)

4	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.
	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.
	The audit team verified that, in the North East office, inspections are planned and are generally performed in accordance with SOP 17 and SOP 6 as required.
	Supervision of the veterinary inspectors and official controls by regional superintending veterinary inspectors are not documented nationally in an SOP, but are discussed by the three regional superintending veterinary inspectors and forms have been agreed. In addition to the two supervisory forms, the regional superintending veterinary inspector has carried out checks on the HACCP official controls using the HACCP form from SOP 17.
5	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
	Non-compliances identified during manufacturer's inspections are recorded on a corrective action report and are followed up by the veterinary inspectors and this was well documented on visit records.
	Onsite verification was carried out in two establishments.
	Establishment 1
	Two Veterinary Inspector AP Audits were carried out in 2015 and identified maintenance and some HACCP non-compliances, but the non-compliance identified by the FSAI audit team in relation to the validation of critical control points and staff training, were not identified. Maintenance non-compliances as identified in the June 2015 Veterinary Inspector AP Report are still significant in this establishment. Official controls samples of microbiological analysis (open pack) are taken by the food business operator and given to DAFM staff which is inconsistent with other establishments.
	Establishment 2
	Two Veterinary Inspector AP Audits were carried out in 2015. The May 2015 audit identified the ice build-up in freezers and this was still open. To comply with the microbiological criteria (n=5), the food business operator is mixing products for a day's production ³ .

³ This should be considered further with the food business operator in terms of compliance with Article 5(1) of Regulation (EC) No 2073/2005

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6	Reports to Food Business Operators
	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.
	The SOP 17 requires audit and inspection reports to be issued following an audit. From the files reviewed, food business operators received a written report in all cases.
7	Verification and Review of Official Controls and Procedures
	Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.
	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.
	Performance monitoring, i.e. the achievement of audit targets against the plan and a review of official controls is carried out by the regional superintending veterinary inspector within the North East office.
	In 2015, the regional superintending veterinary inspector carried out a review of veterinary inspector controls in slaughterhouses and a similar review is planned for standalone premises in 2016. Official controls in two standalone premises were reviewed in 2015. Evidence of joint inspections with the veterinary inspector and the regional superintending veterinary inspector was also seen on the files within the North East region where an issue arises or a change to the approval is required.
	Regional superintending veterinary inspector and veterinary inspectors meetings take place regularly where official controls and documented procedures are discussed. In addition, the regional superintending veterinary inspector attends two meetings with technical staff annually.
	The achievement of the target for other check sheets listed in SOPs, e.g. microbiological, traceability check sheet, is monitored and documented by the regional superintending veterinary inspector when a supervisory audit takes place.
8	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.

	Training in is dependent on a national training plan which is developed annually. Staff interviewed during the audit were knowledgeable of the requirements of the national and EU legislation requirements and also with the procedures.
9	Coordination and Communication
	Recital 16 of Reg. 882/2004 requires competent authorities to 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.
	Art.4.5 of Reg. 882/2004 states 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.
	There is communication between national management, the regional superintending veterinary inspector and the local team regarding targets and inspection numbers.
	Coordination of official controls within the North East region and updates on official control activities is provided via regional and national staff meetings. The audit team was provided with agendas and examples of meetings that had taken place, demonstrating that information was being communicated and disseminated to staff in the region.
10	Registration and Approval
	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 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 3 of regulation 854/ 2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation 882. In addition, Article 3(3) states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.
	The manufacturer's establishment files reviewed were approved as required under Regulation (EC) No 853/2004. One of the food businesses audited had a single approval, although its operations were located on two separate sites.
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4.5. Audit Findings ~ Region 3 South

Official Control Audit Findings			
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) requires that the competent authorities ensure that: they have, or have access to, an adequate laboratory capacity for testing a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively appropriate and properly maintained equipment and facilities legal powers to carry out official controls 		
	A structured approach to the organisation of staff for the performance of official controls is in place within the South region. The region is responsible for carrying out official controls in 31 approved food establishments of which five (one establishment was just approved by DAFM at the time of the audit) are classified as 'ready-to-eat' establishments. The current staff complement in the South region for food control is one superintending veterinary inspector, eight veterinary inspectors, one district superintendent, six senior agricultural officers and 15 technical agricultural officers.		
	Responsibilities for delivery of the food control service is organised by the regional senior veterinary inspector and the district superintendent.		
	Sampling and testing programmes are organised centrally by the relevant DAFM laboratories.		
	Veterinary inspectors were authorised centrally as required and warrants had been issued.		
2	Coordination and Planning		
	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.		
	Risk based priorities for official controls within the South region in 2015 are planned/scheduled in order to meet the requirements of SOP 17 ('ready-to-eat' plants) and SOP 6 (slaughter plants or 'ready-to-eat'/'ready-to-heat' plants attached to slaughter plants) in the case of inspections and in accordance with the national microbiological and chemical analysis sampling plans devised by the laboratories.		
	In 2015, the four 'ready-to-eat' establishments were inspected in line with the rate of inspection required under SOP17 and SOP 6.		

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	Food Business Operator	Risk Rating ^₄	Required Audits	Audits carried out 2015		
	Food Business Operator 1	12	2	2	-	
	Food Business Operator 2	18	2	2	-	
	Food Business Operator 3 (attached to slaughter house)	11	1	1	-	
	Food Business Operator 4 (attached to slaughter house)	11	1	1	-	
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. Routine audit and inspection targets are set following a risk assessment as outlined in SOP 6 and SOP 17. The						
regional superintending veterinary inspector carries out SOP 6 audits in premises attached to slaughterhouses. The regional superintending veterinary inspector schedules audits in standalone establishments. The regional superintending veterinary inspector is copied on risk assessments, audit and corrective action reports. On occasion, the regional superintending veterinary inspector conducts audits in standalone premises in conjunction with the supervisory veterinary inspector.						

⁴ Risk Rating Score 12-14 (2 audits and 2 unannounced inspections), Risk Rating Score 15-17 (2 audits and 3 unannounced inspections) and Risk Rating Score >/18 (2 audits and 4 unannounced inspections)

4	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.
	Article 8(3) states that the competent authorities must have procedures in place to verify the effectiveness of official controls, to ensure corrective action is taken when needed, and to update documentation as appropriate.
	The audit team verified that, in the South region, inspections are planned and are generally performed in accordance with SOP 17 and SOP 6 as required.
	Supervision of the veterinary inspector s and official controls by the regional superintending veterinary inspector is not documented nationally in a SOP but is discussed by the regional superintending veterinary inspectors and forms have been agreed. Three forms are used by the regional superintending veterinary inspector in this region (Audit and Vet Controls and Records – Slaughter, Audit and Vet Controls and Records – Non Slaughter Regional Superintending Veterinary Inspector Audit Form.).
	In 2015, the regional superintending veterinary inspector carried out and documented a supervisory audit of the official controls in one standalone establishment and conducted an advisory visit to the other standalone establishment. Regional Superintending Veterinary Inspector Audits took place in both of the slaughter establishments with cooking facilities in 2015. Routine inspections are carried out by the veterinary inspector.
5	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.
	Non-compliances identified during Superintending Veterinary Inspector Audits are recorded on a corrective action report and are followed up by the veterinary inspector at the next inspection and this was documented on audit records.
	One establishment was audited.
	Two Superintending Veterinary Inspector Audits have taken place in this establishment in 2015. One of the audits was to check veterinary inspector controls and the other audit included a full site inspection and HACCP records and CCPs. Veterinary Inspector AP Audits do not take place as it is attached to a slaughter establishment. Issues identified by the audit team around the cooking CCP, product flow and segregation were not identified during recent audits.

6	Reports to Food Business Operators
	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.
	SOP 17 and SOP 6 require audit and inspection reports to be issued following an audit. From the files reviewed, food business operators received a written report in all cases.
7	Verification and Review of Official Controls and Procedures
	Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.
	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.
	Performance monitoring, i.e. the achievement of audit targets against the plan and a review of official controls, is carried out by the regional superintending veterinary inspector within the South region.
	Evidence of joint inspections with the veterinary inspector and the regional superintending veterinary inspector was also seen on the files within the South region where an issue arises or a change to the approval is required.
	The regional superintending veterinary inspector meets with the district superintendent monthly and regional superintending veterinary inspector/veterinary inspector meetings take place where official controls and documented procedures are discussed.
8	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, 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 competent authorities to ensure that staff receive appropriate training and are kept up-to-date in their competencies.
	Training in is dependent on a national training plan which is developed annually. Staff interviewed during the audit were knowledgeable of the requirements of the national and EU legislation requirements and also with the procedures.

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9	Coordination and Communication
	Recital 16 of Reg. 882/2004 requires competent authorities to 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.
	Art.4.5 of Reg. 882/2004 states 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.
	There is communication between national management, the regional superintending veterinary inspector and the local team regarding targets and inspection numbers.
	Coordination of official controls within the South region and updates on official control activities is provided via regional and national staff meetings. The audit team was provided with agendas and examples of meetings that had taken place, demonstrating that information was being communicated and disseminated to staff in the region.
10	Registration and Approval
	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 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 3 of Regulation (EC) No 854/2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation (EC) No 882/2004. In addition, Article 3(3) states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.
	The manufacturer's establishment files reviewed were approved as required under Regulation (EC) No 853/2004.

5. 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 disseminated nationally to ensure that corrective actions and opportunities for improvement identified are implemented across all regions.



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