

AUDIT
REPORT

Audit of Official Controls in
Manufacturing Establishments
supervised by the Health
Service Executive

SEPTEMBER 2016



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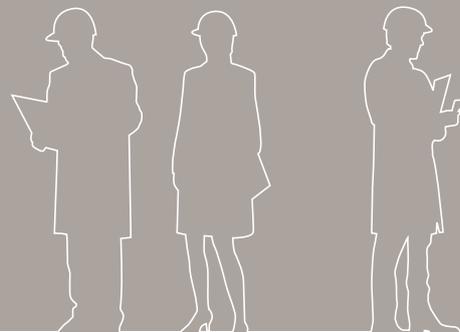


TABLE OF CONTENTS

1.	GLOSSARY	2
2.	EXECUTIVE SUMMARY	3
3.	INTRODUCTION	4
	3.1. Audit Objective	4
	3.2. Audit Scope	4
	3.3. Audit Criteria and Reference Documents	4
	3.4. Audit Methodology	5
4.	AUDIT FINDINGS.....	6
	4.1. Official Controls performed in accordance with Regulation (EC) No 882/2004.....	6
	4.1.1. Organisation and Structure of Official Controls.....	6
	4.1.2. Coordination and Planning	6
	4.1.3. Registration and Approval.....	7
	4.1.4. Prioritisation of Official Controls and Risk Categorisation.....	8
	4.1.5. Documented Procedures	9
	4.1.6. Identification, Follow-up and Close-out of Non-compliances	10
	4.1.7. Reports to Food Business Operators.....	10
	4.1.8. Verification and Review of Official Controls	10
	4.1.9. Staff Performing Official Controls	11
	4.2. Food Business Operator Findings	12
	4.3. Audit Findings ~ Local Area Galway.....	12
	4.4. Audit Findings ~ Local Area Carlow Kilkenny.....	18
	4.5. Audit Findings ~ Local Area, North Cork	23
	4.6. Audit Findings ~ Local Area, Clondalkin.....	29
	4.7. Audit Findings ~ Local Area, Kerry.....	35
5.	AUDIT FINDINGS REQUIRING CORRECTIVE ACTION	41

1. GLOSSARY

FSAI	Food Safety Authority of Ireland
HSE	Health Service Executive

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 controls performed in food manufacturing establishments by the Environmental Health Service of the Health Service Executive (HSE). The audit was undertaken as part of the planned programme of audits carried out by the FSAI in 2015, to determine the level of compliance with European legislation and conformance with the service contract in place between the HSE and the FSAI.

The audit was carried out in five HSE local areas covering all four HSE operational regions. The first part of the audit involved an examination of paperwork associated with official controls, reviewing 50 of the files the HSE Environmental Health Service maintain on food manufacturing establishments including related inspection reports. The second part involved an onsite verification audit of ten food manufacturing establishments selected during the file review.

Overall, the audit concluded that the official controls carried out by the Environmental Health Service in respect of food manufacturing establishments are in compliance with the legislation and there is an organised approach to the identification and follow-up of non-compliances. There was however, an inconsistent approach to the definition of 'manufacturer', e.g. retail units that manufacture on-site are categorised as manufacturers in some areas but as retailers in other areas. The Environmental Health Service annual work plan organises certain official controls by priority business type, e.g. manufacturer, retailer, and therefore, if food business operators are not categorised in the same way across local areas, they will not receive a consistent level of official controls.

The audit identified a number of shortcomings in relation to official controls concerning the approval requirements under Regulation (EC) No 853/2004, HACCP (Regulation (EC) No 852/2004) and the requirements of Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. In the ten food establishments audited, the majority but not all non-compliances under these Regulations had been identified by environmental health officers during previous inspections. Further training for environmental health officers on these Regulations has been identified and planned as part of the Environmental Health Service training plan.

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. The HSE is one of the agencies that has entered into a service contract with the FSAI and is responsible for enforcing food legislation in approximately 44,500 food businesses in Ireland. It is a requirement of food legislation and the service contract and that the HSE ensures official controls are carried out regularly, on a risk basis, and with the appropriate frequency. The audit was carried out in each of the four operational regions of the HSE's Environmental Health Service.

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 HSE in food manufacturing establishments. Compliance by the HSE's Environmental Health 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 also assessed compliance with food law in ten food manufacturing establishments.

This audit was undertaken as part of the FSAI's audit programme for 2015. This report describes the audit's objective, scope, methodology and findings.

3.2. Audit Scope

The audit covered the organisation, planning, implementation and review of official controls within the Environmental Health Service of the HSE at national, regional and local levels in order to confirm compliance with the requirements of Regulation (EC) No 882/2004, the FSAI service contract, the national control plan for Ireland 2012-2016, and the HSE's own documented procedures. As part of this audit, compliance with food law in 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 HSE](#)
- [Food Safety Authority of Ireland Act, 1998](#) (S.I. No. 29 of 1998), as amended
- [Regulation \(EC\) No 882/2004](#) on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- [Regulation \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended
- [Regulation \(EC\) No 853/2004](#) laying down specific hygiene rules for food of animal origin, as amended
- [Regulation \(EC\) No 2073/2005](#) on microbiological criteria for foodstuffs, as amended

Audit of Official Controls in Manufacturing Establishments supervised by the Health Service Executive

SEPTEMBER 2016

- [Regulation \(EU\) No 1169/2011](#) on the provision of food information to consumers
- [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
- [Commission Decision 677/2006](#) setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004

Secondary criteria

- [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](#)
- Service plans and data supplied to the FSAI
- Documented procedures
- Guidance Notes/Codes of Practice
- Other relevant legislation detailed in the FSAI/HSE 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 the HSE, 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 the HSE. The audit started with a meeting with the Environmental Health Services with the four regional chief environmental health officers. The audit team looked for evidence on a national level as to how the Environmental Health Service consistently and effectively delivers its obligations under the service contract, implements Regulation (EC) No 882/2004 and adheres to documented procedures. The audit also looked for evidence to confirm how this monitored and reviewed across all four regions.

Five HSE local areas were then audited. The auditors met with the principal environmental health officer for each local area and environmental health officers to review documented procedures and also the files and inspection reports for ten food manufacturing establishments under that local area's supervision.

The audit team then visited two food manufacturing establishments in each local area, accompanied by the relevant environmental health officers, to assess the organisation, planning and implementation of the official controls 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 one regional chief environmental health officer and principal environmental health officers, 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 (1) and (2) 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 3 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.

Findings

The Environmental Health Service provides a range of food safety/food control services in accordance with the service contract between the FSAI and the HSE. These services include inspection of food businesses and food sampling to ensure compliance with food legislation and the management of food incidents for food businesses. The Environmental Health Service operates nationally under the direction of the Assistant National Director for Environmental Health, regionally under the direction of a regional chief environmental health officer and locally under the direction of a principal environmental health officer. The Environmental Health Service national management team (assistant national director and regional chief environmental health officers) set out the activities and targets to be achieved in the annual Environmental Health Service Business Plan. The principal environmental health officer organises the inspection of food establishments in their local area in line with Environmental Health Service Business Plan priorities and following agreement with the regional chief environmental health officer. If targets are not likely to be achieved the principal environmental health officer reorganises the workload within their area to ensure the highest risk establishments are inspected first. The organisation of official controls in food manufacturing establishments is guided in the main by *Guidance Note No. 1 (Revision 2) Inspection of Food Businesses*¹. Food manufacturing establishments are supervised by environmental health officers in the district they are allocated.

The Environmental Health Service national management team indicated that there is a process underway to reorganise resources nationally to better ensure staff are aligned to priorities and needs.

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.

¹ FSAI/HSE [Guidance for the Health Service Executive on the inspection of food businesses revision 2](#)

Findings

In each local area, official controls are organised and planned on the basis of risk. Inspections are planned/scheduled in order to meet the requirements of *Guidance Note No. 1 (Revision 2)*. Routine sampling is planned in accordance with the *Risk Based Guidance for Routine Microbiological Sampling* and the yearly microbiological and chemical analysis sampling plans.

If inspection or sampling targets are not likely to be met, principal environmental health officers reorganise workload within the office. Access to laboratory capacity is adequate to meet the needs of both the microbiological and chemical sampling plans. Facilities and equipment are in place locally for staff to carry out their work and legal powers and authorisations were in place. Coordination within local areas is arranged effectively by principal environmental health officers and senior environmental health officers and the evidence of meetings and cooperation on inspections was seen on files.

The Environmental Health Service has national groups in place to deal with training, sampling, enforcement consistency, legislation, labelling and the audit team saw evidence that staff in the local areas audited contributed to these groups. Issues raised at these fora were communicated regionally and/or locally.

There is communication between the national management team, the principal environmental health officers and local teams regarding targets and inspection numbers. Coordination of official controls within the local areas and updates on official control activities are provided at staff meetings. Communication from national meetings regarding the legislation committee, consistency and relevant topics are communicated to Environmental Health Service staff. The audit team was provided with agendas and minutes from meetings that had taken place, demonstrating that information was being communicated and disseminated to Environmental Health Service staff.

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

Across the 50 food business files reviewed, food manufacturing establishments were registered under Regulation (EC) No 852/2004 or approved under Regulation EC No 853/2004. One of the establishments audited had two separate registrations; one under the 1950 Food Hygiene Regulations (covering manufacturing activities) and the other registration was provided under Regulation (EC) No 852/2004 (covering wholesaling and distribution activities). In four food manufacturing establishments that handled raw meat, the food business operators had not been requested by the HSE to complete self-declaration forms in order to assess if they required approval under Regulation 853/2004.

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

For all local areas audited, risk-based priorities for official controls are planned in order to meet the requirements of *Guidance Note No.1 (Revision 2)*. Food businesses were risk profiled in accordance with the Guidance Note. Inspection frequencies were carried out at the standard or minimum frequency, based on resources available.

Each local area sets their inspection targets but in 2013, many of these targets were not achieved, even in the higher risk establishments (Categories 1-3). However, this shortfall was identified and addressed at national and local area level, with the result that in 2014, inspection targets were largely achieved (at least 88% of the inspection targets met in Category 1-3 food businesses).

Table 1: Percentage of Inspection Target achieved in 2013 and 2014 applying the rate of inspection set in Guidance Note 1 (Revision 2)²

% of Inspection Target Achieved						
Year	Risk Category	Galway	Carlow/ Kilkenny	North Cork	Clondalkin	Kerry
2014	Category 1	89	100	88	100	100
	Category 2	90	102	119	105	91
	Category 3	125	88	122	97	89
	Category 4	138	102	86	129	144
	Category 5	174	111	76	85	78
2013	Category 1	90	100	70	122	100
	Category 2	82	90	111	71	88
	Category 3	39	81	96	67	98
	Category 4	121	122	37	104	129
	Category 5	1.2	52	80	57	64

² Detailed information by local area is provided in the local area reports (Section 4.3 - 4.7)

Sampling

Food samples are taken for microbiological analysis in accordance with national risk-based guidance introduced in 2013.

Food samples for chemical analysis are taken in accordance with the national annual sampling plan. The sampling plans are reviewed in the local area offices regularly and can be adapted to take into account changing resources, establishment profiles and risk based priorities. In each local area, sampling coordinators were nominated and sampling rotas were in place for environmental health officers.

Water sampling was carried out based on risk and non-compliances were communicated to food business operators. Different systems were in place in local areas depending on agreements with local authorities.

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.

Documented Procedures

FSAI Guidance Note 1 – Guidance for the Health Service Executive on the Inspection of Food Businesses (Revision 2)

Findings

The audit team verified that inspections are planned and are generally performed in accordance with *Guidance Note No. 1 (Revision 2)*. Routine microbiological sampling is carried out in accordance with the *Risk Based Guidance for Routine Microbiological Sampling*. Chemical sampling is carried out according to the chemical sampling plan for the year.

A priority action list was in place in each office and there was documented evidence that this list was reviewed.

Although template letters are in place for issuing findings from inspections to food businesses, these were not used on a small number (4/50 files reviewed) of occasions.

There was an inconsistent approach to the definition of 'manufacturer', e.g. retail units that manufacture on site are categorised as manufacturers in some areas but as retailers in other areas. The Environmental Health Service annual work plan organises certain official controls by priority business type, e.g. manufacturer, retailer and therefore, if food business operators are not categorised in the same way across local areas they will not receive a consistent level of official controls.

Environmental health officers recorded information from inspections differently; some relied on contemporaneous notes and others included the detail on the electronic visit records.

The Environmental Health Service business plan for 2015 requires principal environmental health officers to review inspection files to assess if food control activities are being carried out in line with *Guidance Note No. 1 (Revision 2)* and the HSE's *Protocol 3 'Inspection of a food business'*. As there is little guidance for principal environmental health officers on how to conduct this review, different methods were used across the five local areas audited.

In four food manufacturing establishments that handled raw meat, the food business operators had not been requested by the HSE to complete self-declaration forms in order to assess if they required approval under Regulation (EC) No 853/2004.

The 'Standard Operating Procedure No. 33 Water Sampling of food business' states that the 'National Environmental Health Operational plan shall include national water plan on a yearly basis. Priority shall be given to food business establishments based on a risk assessment of the water supply and the food business establishment.' It is not clear how or who conducts this risk assessment. A document 'Statutory basis for Assessment of Drinking Water Quality in food businesses' is scheduled for finalisation and implementation in the 2015 Environmental Health Service business plan. This might provide further guidance for environmental health officers. At present, different arrangements are in place locally to test water and report on non-compliances.

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

In general, non-compliances are identified by environmental health officers and follow up to non-compliances was well documented on file (50 files were reviewed and non-compliances were documented and closed out in 45 files).

In the ten food establishments audited, the majority of the non-compliances found by the audit team had been identified by environmental health officers during previous inspections. However, some of the non-compliances in relation to HACCP, Regulation (EC) No 853/2004 and Regulation (EC) No 2073/2005 were identified by the audit team and 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 the majority of cases where inspections identified non-compliances, reports were forwarded to food business operators after official control audits. In general, the reports were well documented and issued in a timely manner. In six of the 50 files, non-compliances identified in an inspection report or contemporaneous notes taken by an officer were not reported in writing to the food business operator.

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

The national Environmental Health Service business plan states that in 2015:

- The service will continue to develop its reporting and analysis capabilities from the Environmental Health Information System and focus on developing measures to assess the effectiveness of the service.
- A priority for 2015 will be the implementation of a consistent approach to assessing the effectiveness of the Environmental Health Service including the introduction of structured internal audit.
- Individual file reviews shall be carried out in 2015 to at a minimum assess food control files for compliance with Guidance Note No.1 Revision 2 and Protocol 3 requirements.

At the time of the audit, different systems to verify the effectiveness of official controls were in place in each local area. The regional chief environmental health officer assesses achievement of targets nationally and regionally. The principal environmental health officer and/or senior environmental health officers in each local area assess the achievement of targets against the business plan. Staff environmental health meetings take place where targets are discussed. In each of the local areas audited, the principal environmental health officer and/or the senior environmental health officers had conducted desk-based audits or file reviews on food business operators' files to verify that official controls were being carried out consistently and in line with *Guidance Note No. 1 Revision 2*. Joint inspections may also take place where senior environmental health officers accompany environmental health officers on difficult inspections, food poisoning investigations, etc. Evidence of these joint inspections was seen on the files reviewed.

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 Guidance Note 1 Revision 2 and Environmental Health Service protocols. A training needs assessment had been completed in each local area and returned to regional training representatives for inclusion in the national training plan for 2015.

The non-compliances identified by the audit team in food businesses, highlighted a need for further guidance for environmental health officers on the application of HACCP in small food businesses. The HSE has established a working group to address this. In addition, during the audit, some environmental health officers interviewed requested further training on Regulation (EC) No 2073/2005 and the 'Marginal Localised and Restricted' exemption. These requirements have been identified in the 2015 training plan.

Service Contract requirements

Findings

Review of the files showed that official controls are being carried out on non-hygiene legislation covered in the service contract, although at varying levels for legislation on food contact materials and labelling. The development and implementation of a work plan in the service contract liaison process seeks to address this.

4.2. Food Business Operator Findings

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

4.3. Audit Findings ~ Local Area Galway

Official Control Audit Findings	
1	<p>Organisation and Structure of Official Controls</p> <p>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.</p> <p>Article 4(2) requires that the competent authorities ensure that:</p> <ul style="list-style-type: none">• 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 <p>A structured approach to the organisation of staff for the performance of official controls was in place. This local area is responsible for carrying out official controls in 2,969 food establishments. The current whole time equivalent for food control is 14, including the principal environmental health officer (2 whole time equivalent less than in January, 2015).</p> <p>Responsibilities for delivery of the food control service is organised by the principal environmental health officer and three senior environmental health officers. In addition to the supervision of food businesses, senior environmental health officers also supervise environmental health teams and are responsible for assessing if the targets and official control functions in those teams are met.</p> <p>Each environmental health officer is responsible for the supervision of an allocated number of establishments and for conducting all official controls (including complaints, outbreaks, labelling etc.) related to those establishments.</p> <p>One senior environmental health officer is responsible for administering the sampling programmes. Cover for statutory leave arrangements is organised within the senior environmental health officer teams.</p> <p>This local area confirmed they have adequate laboratory capacity for testing. Environmental health officers were authorised as required and warrants had been issued.</p>

2	<p>Coordination and Planning</p> <p>Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.</p> <p>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.</p> <p>Risk-based priorities for official controls within the local area in 2015, are planned/scheduled in order to meet the standard inspection targets set in <i>Guidance Note No. 1 (Revision 2)</i>.</p> <p>It was evident from the ten files reviewed by the audit team that in 2014, food manufacturing establishments were regularly inspected in line with the standard rate of inspection for the relevant risk category</p> <p>A copy of the environmental health targets to be achieved for all food business supervised by the Galway local area for 2014 and 2013 were provided to the audit team. These are summarised in Table 2. In addition, a local target of 45 inspections per environmental health officer per quarter is set, which includes planned surveillance work but not complaints and unplanned work.</p> <p>Table 2: Galway Local Area - Inspection achieved applying the standard rate of inspection set in Guidance Note No.1 (Revision 2)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Food Business Risk Category</th> <th colspan="3">2014</th> <th colspan="3">2013</th> </tr> <tr> <th>Number of inspections carried out/target number of inspections</th> <th>+/-</th> <th>% of target achieved</th> <th>Number of inspections carried out/target number of inspections</th> <th>+/-</th> <th>% of target achieved</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>16 /18</td> <td>-2</td> <td>89%</td> <td>18/20</td> <td>-2</td> <td>90%</td> </tr> <tr> <td>2</td> <td>354/394</td> <td>-40</td> <td>90%</td> <td>325/352</td> <td>-27</td> <td>92%</td> </tr> <tr> <td>3</td> <td>1,093/873</td> <td>+220</td> <td>125%</td> <td>510/1312</td> <td>-802</td> <td>39%</td> </tr> <tr> <td>4</td> <td>674/487</td> <td>+187</td> <td>138%</td> <td>427/354</td> <td>+73</td> <td>121%</td> </tr> <tr> <td>5</td> <td>600/345</td> <td>+255</td> <td>174%</td> <td>7/566</td> <td>-559</td> <td>1.2%</td> </tr> </tbody> </table> <p>Routine food sampling is planned in accordance with the <i>Risk Based Guidance for Routine Microbiological Sampling</i> and the 2015 microbiological and chemical analysis sampling plans. A water sampling plan is in place for food businesses for 2015. A sampling rota was in place in the local area to organise sampling by environmental health officers.</p>	Food Business Risk Category	2014			2013			Number of inspections carried out/target number of inspections	+/-	% of target achieved	Number of inspections carried out/target number of inspections	+/-	% of target achieved	1	16 /18	-2	89%	18/20	-2	90%	2	354/394	-40	90%	325/352	-27	92%	3	1,093/873	+220	125%	510/1312	-802	39%	4	674/487	+187	138%	427/354	+73	121%	5	600/345	+255	174%	7/566	-559	1.2%
Food Business Risk Category	2014			2013																																													
	Number of inspections carried out/target number of inspections	+/-	% of target achieved	Number of inspections carried out/target number of inspections	+/-	% of target achieved																																											
1	16 /18	-2	89%	18/20	-2	90%																																											
2	354/394	-40	90%	325/352	-27	92%																																											
3	1,093/873	+220	125%	510/1312	-802	39%																																											
4	674/487	+187	138%	427/354	+73	121%																																											
5	600/345	+255	174%	7/566	-559	1.2%																																											
3	<p>Prioritisation of Official Controls and Risk Categorisation</p> <p>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.</p>																																																

	<p>Routine inspection targets are set in Guidance Note 1 (Revision 2). The principal environmental health officer meets with the senior environmental health officer Team regularly to review inspections, targets, food business files, and to discuss official controls for the office. A priority action list is in place. Targets are also discussed at all-staff information meetings. Targets are monitored when compiling quarterly returns for national management in the Environmental Health Service as these results indicate if official controls are being carried out in line with the targets set in <i>Guidance Note No. 1 (Revision 2)</i>. Table 2, shows that in 2014, the target inspection rate was not met for Category 2 establishments and for Category 3 establishments in 2013³. Performance monitoring, i.e. the achievement of targets against the plan, and a review of official controls are carried out by the senior environmental health officers on a one-to-one basis with the environmental health officers. In order to standardise these meetings for 2015, a template agenda has been developed.</p>
4	<p>Documented Procedures</p> <p>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.</p> <p>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.</p> <p>The audit team verified that inspections are planned and are generally performed in accordance with the frequencies set in <i>Guidance Note No. 1 (Revision 2)</i>.</p> <p>It was noted by the audit team that one establishment classified as a food manufacturing establishment, was a café/retailer.</p> <p>Non-compliances identified in one food manufacturing establishment had not been issued in writing to the food business operator following an inspection as required by <i>Guidance Note No. 1 (Revision 2)</i>. Nevertheless, notes on telephone conversations and evidence of emails with compliance information were sent to the food business operator and these were available on the file⁴.</p> <p>Routine microbiological sampling is carried out in accordance with the <i>Risk Based Guidance for Routine Microbiological Sampling</i>. Chemical sampling is carried out according to the chemical sampling plan for the year. The sampling plans are reviewed in the office on an on-going basis and are adaptable to facilitate changing resources, establishment profiles and risk-based priorities.</p> <p>The local area has a documented approach to sampling and testing water in food businesses, based on the risk of the water supply, i.e. public, group or private.</p> <p>A number of environmental health protocols/documented procedures were audited:</p> <ul style="list-style-type: none">• Protocol 39 Calibration: Calibration is done in-house unless a thermometer fails. The master thermometer is calibrated externally. The thermometers examined were in calibration• Protocol 14 Export Certs: Exports certs were issued in line with procedures• Protocol 4 Complaints: Complaints were logged and closed off in line with procedures

³ Corrective actions were taken in the first quarter of the following year to address outstanding inspections.

⁴ Following the audit, a letter was issued by the environmental health officer on 16/06/15, to follow up on non-compliances identified in the previous inspection

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 inspections of food manufacturing establishments are followed up as per the FSAI's *Guidance Note No. 1 (Revision 2)*, and this was verified by the audit team on the ten food business files reviewed.

Findings identified during an inspection are assessed at the next inspection to confirm they have been closed out, and this was well documented on the visit records reviewed by the audit team.

A priority action list is in place and is reviewed and managed in line with the FSAI's *Guidance Note No. 1 (Revision 2)*. The audit team noted two incidences where food business remained on the priority action list for an extended period of time:

- In one food manufacturing establishment, minor non-compliances were identified in September 2013. In June, 2014, the establishment was included on the priority action list because the condition in the premises had deteriorated. The audit team noted that seven inspections had taken place in this establishment between September 2013 and March 2015, but the non-compliances were not closed out, nor was further enforcement action taken, and the business remains on the priority action list. While the serious non-compliances have been addressed, minor non-compliances (structural) remain open. The principal environmental health officer explained that the food business was due to move location in order to address the structural non-compliances, but this did not proceed for commercial reasons. The food business operator maintains that he is due to relocate the business
- In December 2014, an Improvement Notice served on an establishment with a compliance period of 12 weeks. However, the notice was still in place at the time of the audit (June 2015). The principal environmental health officer explained that the food business operator was given an extension to the timeframe of the original notice for the completion of structural work⁵

In the two food manufacturing establishments visited by the audit team:

- Establishment 1 (risk Category 2): A number of minor non-compliances were identified in relation to the application of the HACCP system, traceability and maintenance/cleaning. The official control inspections identified some of these non-compliances but the HACCP non-compliances had not been identified (two inspections in 2014, both satisfactory) and the cleaning/maintenance non-compliances identified previously by the Environmental Health Service (during 2013 inspection) were still open⁶
- Establishment 2 (risk Category 1): No non-compliances were identified in the establishment on the day the audit team visited

⁵ Improvement Notice was lifted on 23/06/15

⁶ The HACCP plan has been updated to detail the corrective actions to be taken in the event a critical limit is not met (update from Environmental Health Service, April 2016)

6.	<p>Reports to Food Business Operators</p> <p>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.</p> <p>The national protocol requires inspection reports to be issued when non-compliances are found. From the files on food manufacturing establishments reviewed, food business operators received a written report in all cases where inspections identified non-compliances. The local area's own protocol is to issue a written report following all inspections, including those with a satisfactory outcome.</p>
7.	<p>Verification and Review of Official Controls and Procedures</p> <p>Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.</p> <p>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.</p> <p>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.</p> <p>Performance monitoring, i.e. the achievement of targets against the plan, and a review of official controls are carried out by the principal environmental health officer and senior environmental health officers within the local area office. Targets are discussed at staff meetings. In 2013 and 2014, the principal environmental health officer and senior environmental health officers carried out a desk-based audit on food business operators' files to verify that official controls were being carried out consistently, and in line <i>Guidance Note No.1 (Revision 2)</i>. A formal file review is again scheduled in the business plan for 2015 (Q3/4).</p> <p>Joint inspections may also take place where senior environmental health officers accompany environmental health officers on difficult inspections, food poisoning investigations, etc. The audit team saw evidence of these joint inspections on the food business files reviewed.</p>
8.	<p>Staff Performing Official Controls</p> <p>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.</p> <p>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.</p> <p>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 national and EU legislation requirements and also with <i>Guidance Note No. 1 (Revision 2)</i> and Environmental Health Service</p>

Audit of Official Controls in Manufacturing Establishments supervised by the Health Service Executive

SEPTEMBER 2016

	<p>protocols. An annual training needs assessment has been completed for Environmental Health Service staff and returned for inclusion in the national training plans.</p>
<p>9.</p>	<p>Coordination and Communication</p> <p>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.</p> <p>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.</p> <p>The audit team saw evidence of communication between national management (regional chief environmental health officer), the principal environmental health officer and the local team regarding targets and inspection numbers.</p> <p>Coordination of official controls within the local area and updates on official control activities is provided by staff at staff meetings. The principal environmental health officer has allocated a member of the team to keep a watching brief on each of the main national committees, e.g. enforcement consistency, labelling. The audit team was provided with agendas and examples of meetings that had taken place, demonstrating that information from these national committees was being communicated and disseminated to the Environmental Health Service in the local area.</p>
<p>10.</p>	<p>Registration and Approval</p> <p>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.</p> <p>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.</p> <p>The audit confirmed that all except one of the ten food manufacturing establishment files reviewed were registered under Regulation (EC) No 852/2004 or approved under Regulation (EC) No 853/2004 as required. One establishment had two separate registrations: one under the 1950's Food Hygiene Regulations (covering manufacturing activities) and the other registration was provided under Regulation (EC) No 852/2004 (covering wholesaling and distribution activities).</p>

Service Contract requirements

Official controls in relation to non-hygiene legislation of the service contract was evident on the files.

4.4. Audit Findings ~ Local Area Carlow Kilkenny

Official Control Audit Findings	
1	<p>Organisation and Structure of Official Controls</p> <p>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.</p> <p>Article 4(2) requires that the competent authorities ensure that:</p> <ul style="list-style-type: none"> • 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 <p>A structured approach to the organisation of staff for the performance of official controls was in place within the local area. This local area is responsible for carrying out official controls in 1,202 food establishments, 1,322 when Category 6 food business operations are included. The current whole time equivalent for food control is approximately ten, including the principal environmental health officer and two senior environmental health officers.</p> <p>The delivery of the food control service is organised by the principal environmental health officer and senior environmental health officers. In addition to the supervision of food establishments, senior environmental health officers supervise two environmental health teams. The senior environmental health officers are responsible for monitoring targets and organising official control functions in their teams. Cover for leave arrangements is organised within these senior environmental health officer teams.</p> <p>Each environmental health officer is responsible for the supervision of an allocated number of establishments and for conducting all official controls (including complaints, outbreaks, labelling, sampling plans etc.) related to those establishments.</p> <p>The local area confirmed it has adequate laboratory capacity for testing. Environmental health officers were authorised as required and warrants had been issued.</p>
2	<p>Coordination and Planning</p> <p>Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.</p> <p>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.</p> <p>Risk-based priorities for inspections within the Carlow Kilkenny local area for 2015, are planned/scheduled in order to meet the standard inspection targets set in <i>Guidance Note No. 1 (Revision 2)</i>. The file review conducted by the audit team for ten food manufacturing establishments provided evidence that in 2014, they were regularly inspected in line with the standard rate of inspection for the relevant risk category.</p>

Audit of Official Controls in Manufacturing Establishments supervised by the Health Service Executive

SEPTEMBER 2016

In total, 144 inspections per environmental health officer (one whole time equivalent) are planned per year. This target does not include complaints and unplanned work. A copy of the number of inspections achieved for the local area in 2014 and 2013 were provided to the audit team and are outlined in Table 3.

Table 3: Carlow Kilkenny Local Area - Inspection achieved applying the standard rate of inspection set in Guidance Note 1 (Revision 2)

Food Business Risk Category	2014			2013		
	Number of inspections carried out/target number of inspections	+/-	% of target achieved	Number of inspections carried out/target number of inspections	+/-	% of target achieved
1	16/16	0	100%	16/16	0	100%
2	122/124	+2	102%	134/121	-13	90%
3	617/540	-77	88%	543/441	-102	81%
4	250/255	+5	102%	214/261	+47	122%
5	140/156	-16	111%	242/126	-116	52%

Routine food sampling is planned in accordance with the *Risk Based Guidance for Routine Microbiological Sampling* and the 2015 microbiological and chemical analysis sampling plans. A water sampling plan is in place for food businesses for 2015. A sampling rota was in place in the office to organise sampling by environmental health officers.

3 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 inspection targets are set in line with *Guidance Note No.1 (Revision 2)*. The principal environmental health officer meets with the senior environmental health officer team regularly to review inspections, targets, food business files, and to discuss official controls for the local area. A priority action list is in place.

Table 3 shows that the target inspection rate was not met for Category 3 food businesses in 2013 or 2014. However, the target number of inspections was largely achieved for food businesses in Categories 1, 2 and 4.

Briefing sessions or all-staff information meetings are arranged every two months. Targets are monitored by the principal environmental health officer and senior environmental health officer and this information is used to assess if official controls are being carried out in line with the targets set in *Guidance Note No. 1 (Revision 2)*.

Performance monitoring, i.e. the achievement of targets against the plan, and a review of official controls is carried out by the senior environmental health officers on a one-to-one basis with the environmental health officers every two months. A template agenda to standardise these reviews has been developed. The

Audit of Official Controls in Manufacturing Establishments supervised by the Health Service Executive

SEPTEMBER 2016

	<p>principal environmental health officer also conducts, at random, two file reviews per month, one from each team. On occasion, an environmental health officer will request that a file is reviewed. At the time of the audit, ten Category 3 food businesses (including early year services and restaurants) had been identified through performance monitoring, as overdue for inspections. The audit team saw evidence that arrangements had been put in place across the two teams to ensure these food businesses are supervised as a matter of priority.</p>
<p>4</p>	<p>Documented Procedures</p> <p>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.</p> <p>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.</p> <p>The audit team verified that, inspections are planned and are generally performed in accordance with <i>Guidance Note No.1 (Revision 2)</i>.</p> <p>Routine microbiological sampling is carried in accordance with the <i>Risk Based Guidance for Routine Microbiological Sampling</i>. Routine chemical sampling is carried out according to the chemical sampling plan for the year. The sampling plans are reviewed in the office on an on-going basis and are adaptable to take into account changing resources, establishment profiles and risk-based priorities.</p> <p>It was noted by the audit team that one establishment classified as a food manufacturing establishment could be more accurately classed as a retail establishment as it only supplied retail customers.</p> <p>A number of environmental health protocols/documented procedures were audited:</p> <ul style="list-style-type: none"> • Protocol 39 Calibration: environmental health officers are responsible for the calibration of their own thermometer. The senior environmental health officer verifies all thermometers are calibrated every six months. If a thermometer fails this check it is sent for external calibration. The master thermometer is calibrated externally. Records reviewed indicated that thermometers were in calibration • Protocol 14 Export Certs: Exports certs reviewed are being issued in line with procedures • Protocol 4 Complaints: Complaints reviewed were being logged and closed off in line with procedures
<p>5</p>	<p>Identification, Follow-up and Close-out of Non-compliances</p> <p>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.</p> <p>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.</p> <p>Non-compliances identified during inspections of food manufacturing establishments are followed up as per <i>Guidance Note No.1 (Revision 2)</i> and this was verified by the auditors on the ten files reviewed. Findings</p>

	<p>from previous inspections are assessed for their close-out at the next inspection and this was documented on 7/10 files reviewed. In the other three food businesses, follow-up inspections had taken place but the close-out of previous non-compliances was not documented. For example, minor non-compliances were identified in one food business in March 2014 but remained open at the most recent inspection in May 2015.</p> <p>In the two food manufacturing establishments visited by the audit team, the following points were noted:</p> <ul style="list-style-type: none"> • Establishment 1 (risk Category 1). Regulation (EC) No 2073/2005 and HACCP non-compliances were identified during previous official control inspections. However, non-compliances relating to shelf-life, environmental monitoring, trending results, controls for chlorine residual levels identified on the day of the audit had not been identified by official controls at the establishment • Establishment 2 (risk Category 1). The range of products produced at this food manufacturing establishment had increased since the last inspection. On the day of the audit, non-compliances were identified in relation to HACCP, traceability and maintenance/cleaning which had not been identified at previous inspections. On-going structural, hygiene as well as Regulation 2073/2005 issues, were evident. Non-compliances identified during previous inspections remained open
<p>6</p>	<p>Reports to Food Business Operators</p> <p>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.</p> <p>The national protocol requires inspection reports to be issued when non-compliances are found. From the files on food manufacturing establishments reviewed by the audit team, food business operators received a written report in the majority of cases where inspections identified non-compliances. However, on two occasions, minor non-compliances were identified in one food manufacturing establishment but only verbal advice was given.</p>
<p>7</p>	<p>Verification and Review of Official Controls and Procedures</p> <p>Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.</p> <p>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.</p> <p>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.</p> <p>Performance monitoring, i.e. the achievement of targets against the plan, and a review of official controls are carried out by the principal environmental health officer and senior environmental health officers within the local area. Staff meetings take place where targets are discussed.</p>

	<p>The principal environmental health officer carries out a desk-based audit using a standardised questionnaire on food business operators' files to verify that official controls were being carried out consistently, and in line <i>Guidance Note No.1 (Revision 2)</i>.</p> <p>Joint inspections also take place where senior environmental health officers accompany environmental health officers on difficult inspections, food poisoning investigations, etc. Evidence of these joint inspections was seen on the files.</p>
<p>8</p>	<p>Staff Performing Official Controls</p> <p>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.</p> <p>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.</p> <p>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 national and EU legislation requirements and also with <i>Guidance Note No.1 (Revision 2)</i> and Environmental Health Service protocols. An annual training needs assessment has been completed for Environmental Health Service staff annually and returned for inclusion in the national training plans.</p>
<p>9</p>	<p>Coordination & Communication</p> <p>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.</p> <p>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.</p> <p>The audit team saw evidence of communication between national management, the principal environmental health officer and the local team regarding targets and inspection numbers.</p> <p>Coordination of official controls within the local area and updates on official control activities are provided by staff at staff meetings. The audit team was provided with agendas and minutes of meetings that had taken place, demonstrating that information was being communicated and disseminated to environmental health staff in the office.</p> <p>A number of staff in the local area are members of nationally coordinated committees including those on sampling, enforcement consistency, food legislation and training. The audit team saw evidence that information from these meetings is communicated to the rest of the staff at staff meetings.</p>

10.	<p>Registration and Approval</p> <p>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.</p> <p>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.</p> <p>The review of ten food manufacturing establishment files by the audit team confirmed that all were registered under Regulation (EU) No 852/2004. One of the food manufacturing establishments visited by the audit team cooked small volumes of raw foods of animal origin and was wholesaling the products, with no retail sales from the business. However, the audit team did not see any evidence that the food business operator had been requested to complete a self-declaration form in order to assess if this manufacturer should also be approved under Regulation (EC) No 853/2004.</p>
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Service Contract requirements

Official controls in relation to non-hygiene legislation of the service contract were evident on the files.

4.5. Audit Findings ~ Local Area, North Cork

Official Control Audit Findings	
1.	<p>Organisation and Structure of Official Controls</p> <p>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.</p> <p>Article 4(2) requires that the competent authorities ensure that:</p> <ul style="list-style-type: none">• 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 <p>A structured approach to the organisation of staff for the performance of official controls was in place. This local area is responsible for carrying out official controls in 773 food establishments.</p> <p>The current whole time equivalent for food control is approximately three whole time equivalent including the principal environmental health officer. The full complement of staff in the office is 0.9 principal environmental health officer, one senior environmental health officer and eight environmental health officers. At the time of the audit, two environmental health officers were on statutory leave. Responsibilities for delivery of the food control service is organised by the principal environmental health officer and the senior environmental health officer. The principal environmental health officer is responsible for monitoring targets and the overall</p>

Audit of Official Controls in Manufacturing Establishments supervised by the Health Service Executive

SEPTEMBER 2016

	<p>supervision of the official control functions in the local area. Each environmental health officer is responsible for the supervision of their allocated numbers of establishments and for conducting all official controls (including complaints, outbreaks, labelling, sampling plans etc.) related to those establishments. Cover for leave arrangements is organised by the principal environmental health officer. A rota is in place for reactive work if an environmental health officer is on leave and routine inspections of food businesses are reallocated within the team. The audit team saw evidence on visit records and inspection reports that findings identified in a food business by one environmental health officer were followed up by a 'covering' environmental health officer at the next inspection.</p> <p>The local area confirmed it has adequate laboratory capacity for testing.</p> <p>Environmental health officers were authorised as required and warrants had been issued.</p>																																																
2.	<p>Coordination and Planning</p> <p>Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.</p> <p>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.</p> <p>Risk-based priorities for official controls within the North Cork local area in 2015 are planned/scheduled in order to meet the minimum inspection targets set in <i>Guidance Note No.1 (Revision 2)</i>. The ten food manufacturing establishment files reviewed provided evidence that in 2014, they were inspected in line with at least the minimum rate of inspection for the relevant risk category. It was noted that the minimum rate of inspection was not met in two Category 3 establishments; however, these were very small food businesses which operated intermittently.</p> <p>The audit team was provided with a copy of the inspections achieved for all food businesses in the local area for 2014 and 2013. These are outlined in Table 4. The target included planned and planned surveillance inspections but not complaints and unplanned work. Inspection targets are agreed annually with each environmental health officer and are documented and reviewed on a 'work activity' sheet monthly.</p> <p>Table 4: North Cork Local Area - Inspection achieved applying the standard rate of inspection set in Guidance Note 1 (Revision 2)</p> <table border="1"> <thead> <tr> <th rowspan="2">Food Business Risk Category</th> <th colspan="3">2014</th> <th colspan="3">2013</th> </tr> <tr> <th>Number of inspections carried out/target number of inspections</th> <th>+/-</th> <th>% of target achieved</th> <th>Number of inspections carried out/target number of inspections</th> <th>+/-</th> <th>% of target achieved</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>8/7</td> <td>-1</td> <td>88%</td> <td>10/7</td> <td>-3</td> <td>70%</td> </tr> <tr> <td>2</td> <td>48/57</td> <td>+9</td> <td>119%</td> <td>56/62</td> <td>+6</td> <td>111%</td> </tr> <tr> <td>3</td> <td>156/191</td> <td>+35</td> <td>122%</td> <td>171/164</td> <td>-7</td> <td>96%</td> </tr> <tr> <td>4</td> <td>129/111</td> <td>-18</td> <td>86%</td> <td>234/86</td> <td>-148</td> <td>37%</td> </tr> <tr> <td>5</td> <td>85/65</td> <td>-20</td> <td>76%</td> <td>56/45</td> <td>-11</td> <td>80%</td> </tr> </tbody> </table>	Food Business Risk Category	2014			2013			Number of inspections carried out/target number of inspections	+/-	% of target achieved	Number of inspections carried out/target number of inspections	+/-	% of target achieved	1	8/7	-1	88%	10/7	-3	70%	2	48/57	+9	119%	56/62	+6	111%	3	156/191	+35	122%	171/164	-7	96%	4	129/111	-18	86%	234/86	-148	37%	5	85/65	-20	76%	56/45	-11	80%
Food Business Risk Category	2014			2013																																													
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4	129/111	-18	86%	234/86	-148	37%																																											
5	85/65	-20	76%	56/45	-11	80%																																											

	<p>At the time of the audit, all Category 1 and Category 2 food establishments had received at least one inspection in 2015. All Category 3 food manufacturing establishments had been inspected within the last 12 months. All Category 4 and Category 5 establishments had been inspected in either 2014 or 2015. There were a small number of Category 4 and 5 food businesses (generally licenced premises) overdue inspections since 2009, 2010 or 2011. This was identified in 2014 (staff meeting minutes, August 2014) and is in the process of being addressed during 2014 and 2015.</p> <p>Routine food sampling is planned in accordance with the <i>Risk-Based Guidance for Routine Microbiological Sampling</i> and the 2015 microbiological and chemical sampling plans. A sampling rota is in place in the office to facilitate this.</p> <p>The local area compiles a list of food businesses that use private water supplies and by agreement with the County Council, tests these water supplies once per year and follow up on unsatisfactory results. The water supplies of food businesses that use water as a main ingredient are also tested. Again, a sampling plan is in place to organise water sampling. Each year, the office forwards the results testing of private water supplies to the local authority as well as any follow up taken in the case results were unsatisfactory.</p> <p>The principal environmental health officer reviews all test results on a regular basis and maintains a log of unsatisfactory results as they are received.</p>
3.	<p>Prioritisation of Official Controls and Risk Categorisation</p> <p>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.</p> <p>Routine inspection targets are set down in <i>Guidance Note No.1 (Revision 2)</i>. The principal environmental health officer meets with the senior environmental health officer and the environmental health officer team regularly to review inspections, targets and to discuss the organisation of official controls carried out by the local area.</p> <p>The target inspection rate was largely met for Category 1, 2 and 3 food businesses in 2013 and 2014. In 2013 and 2014, an inspection rate of 37% and 86% respectively, was achieved for Category 4 food businesses, but this has been identified by the principal environmental health officer and premises not inspected for an extended period of time are being addressed.</p> <p>A priority action list is in place. The audit team saw evidence that this is reviewed, with the result that no food businesses remain on the list for extended periods of time.</p> <p>Staff meetings are held 3-4 times per year. Targets are agreed at the start of the year based on the projected whole time equivalent available and are monitored by the principal environmental health officer using monthly work activity sheets and quarterly returns to the FSAI. In addition, the principal environmental health officer runs reports to check the next inspection due date to assess if premises are being inspected in line with the targets.</p> <p>Performance monitoring, i.e. the achievement of targets against the plan, and a review of official controls are carried out by the principal environmental health officer on a one-to-one basis with the environmental health officers every six months. A template for this review has been developed and is completed for each environmental health officer.</p>

4.	<p>Documented Procedures</p> <p>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.</p> <p>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.</p> <p>The audit team verified that in the local area, inspections are planned and are generally performed in accordance with the minimum rate set in <i>Guidance Note No.1 (Revision 2)</i>. Routine microbiological sampling is carried out in accordance with the <i>Risk-Based Guidance for Routine Microbiological Sampling</i>. In one food manufacturing establishment file reviewed, the letter to inform the food business operator of non-compliances identified during an inspection was written using an old template and not the current template, although the correct template was used in subsequent inspections.</p> <p>Routine microbiological sampling is carried out in accordance with the <i>Risk-Based Guidance for Routine Microbiological Sampling</i>. Chemical sampling is carried out according to the chemical sampling plan for the year. The sampling plans are reviewed in the office on an on-going basis and are adaptable/flexible to take into account changing resources, establishment profiles and risk-based priorities. Water sampling is conducted in accordance with the local area's documented procedure.</p> <p>It was noted by the audit team that two establishments classified as food manufacturers were supplying the final consumer only, i.e. therefore, they were retail establishments. A number of environmental health protocols/documented procedures were audited:</p> <ul style="list-style-type: none">• Protocol 39 Calibration: Internal calibration is carried out on all thermometers every six months using a master thermometer. If a thermometer fails this check it is sent for external calibration. The master thermometer is calibrated externally. Records reviewed indicated that thermometers were in calibration• Protocol 14 Export Certs: Exports certs reviewed are being issued in line with procedures• Protocol 4 Complaints: Complaints reviewed were being logged and closed off in line with procedures
5.	<p>Identification, Follow-up and Close-out of Non-compliances</p> <p>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.</p> <p>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.</p> <p>The audit team verified that non-compliances identified during inspections are followed up as per <i>Guidance Note No. 1 (Revision 2)</i>, and this was verified by the audit team on the ten food manufacturing establishment files reviewed. Findings from previous inspections are assessed for their close-out at the next inspection and this was generally documented in the visit record or on the letter to the food business operator. In one case, the letter used was an old template which did not make clear to the food business operator if the issues raised were non-compliances against food law or recommendations.</p>

	<p>In the two food manufacturing establishments visited by the audit team, the following points were noted:</p> <ul style="list-style-type: none"> • Establishment 1 (risk Category 1): Maintenance non-compliances were identified on the day of the audit which had been identified previously by the Environmental Health Service during official control inspections, but were not yet closed out • Establishment 2 (risk Category 3): At the last inspection, the food business operator had been given eight weeks to comply with documentary and structural non-compliances. On the day of the audit, the standard of hygiene in the premises was very poor and significant non-compliances were identified by the audit team in relation to the application of HACCP, traceability, structure, and maintenance/cleaning. An Improvement Notice⁷ was issued the day after the audit by the Environmental Health Service and the food business operator was given one week to comply with legal requirements⁸
6.	<p>Reports to Food Business Operators</p> <p>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.</p> <p>The national protocol requires inspection reports to be issued when non-compliances are found. From the ten food manufacturing establishments files reviewed, food business operators received a written report in all cases where non-compliances were identified. Letters were also sent to the food business operator when the inspection was satisfactory as written confirmation of the result of inspection.</p>
7.	<p>Verification and Review of Official Controls and Procedures</p> <p>Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.</p> <p>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.</p> <p>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.</p> <p>Performance monitoring, i.e. the achievement of targets against the plan, and a review of official controls is carried out by the principal environmental health officer in the local area. Targets are discussed at staff meetings.</p> <p>In 2014/2015, the principal environmental health officer carried out a desk-based audit, using a standardised questionnaire on food business files to verify that official controls were being carried out consistently and in line <i>Guidance Note No.1 (Revision 2)</i>.</p>

⁷ An Improvement notice served under Section 52 (1) of the FSAI Act, 1998 is a legal notice served on the proprietor or person in charge of a business directing them to comply with the law.

⁸ Improvement notice was served on the 4 July 2015 and complied with on the 10 July 2015

Audit of Official Controls in Manufacturing Establishments supervised by the Health Service Executive

SEPTEMBER 2016

	<p>Joint inspections may also take place where senior environmental health officers accompany environmental health officers on difficult inspections, out-of-hours inspections, food poisoning investigations, etc. Evidence of these joint inspections was seen on the food business files.</p>
8.	<p>Staff Performing Official Controls</p> <p>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.</p> <p>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.</p> <p>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 national and EU legislation requirements and also with <i>Guidance Note No.1 (Revision 2)</i> and Environmental Health Service protocols. An annual training needs assessment has been completed for Environmental Health Service staff and this has been returned for inclusion in the national training plan.</p>
9.	<p>Coordination and Communication</p> <p>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.</p> <p>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.</p> <p>The audit team saw evidence of communication between national management, the principal environmental health officer and the local team regarding targets, inspection numbers and official controls activity.</p> <p>Coordination of official controls within the local area and updates on official control activities are provided by staff at staff meetings. The audit team was provided with examples agendas and minutes of meetings that had taken place, demonstrating that information from national committees on sampling, enforcement consistency, food legislation, training etc. was being communicated and disseminated to environmental health staff in the local area.</p>
10.	<p>Registration and Approval</p> <p>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.</p> <p>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.</p>

	<p>The review of ten food manufacturing establishment files by the audit team confirmed that all were registered under Regulation (EC) No 852/2004.</p> <p>At the time of the audit, the principal environmental health officer was awaiting clarification from the FSAI as to whether one food manufacturing establishment that is wholesaling foods of animal origin, requires approval under Regulation (EC) No 853/2004.</p>
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Service Contract requirements

Official controls in relation to non-hygiene legislation of the service contract were evident on the files and in particular, labelling. There was limited documented evidence of official controls in relation to food contact materials.

4.6. Audit Findings ~ Local Area, Clondalkin

Official Control Audit Findings	
1.	<p>Organisation and Structure of Official Controls</p> <p>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.</p> <p>Article 4(2) requires that the competent authorities ensure that:</p> <ul style="list-style-type: none"> • 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 <p>A structured approach for the organisation of staff for the performance of official controls was in place. The local area is responsible for carrying out official controls in 581 food establishments.</p> <p>Responsibilities for delivery of the food control service is organised by the principal environmental health officer and the senior environmental health officer. The food control team consists of seven staff including one senior environmental health officer and one principal environmental health officer. The current whole time equivalent for food control is approximately five whole time equivalent. One senior environmental health officer (0.25 whole time equivalent) carries out the training administrative function regionally and locally. Cover for leave arrangements is organised by pairing environmental health officers within the team using a 'buddy' system. Two environmental health officers are currently on statutory leave.</p> <p>The principal environmental health officer and the senior environmental health officer are responsible for local monitoring of environmental health officers' targets and official control functions in the team. The senior environmental health officer is responsible for the administration of the sampling programme for the office. Each environmental health officer is responsible for the supervision of their allocated number of</p>

Audit of Official Controls in Manufacturing Establishments supervised by the Health Service Executive

SEPTEMBER 2016

	<p>establishments and for conducting all official controls (including complaints, outbreaks, labelling, sampling plans etc.) related to those establishments.</p> <p>The office confirmed it has adequate laboratory capacity for testing. Environmental health officers were authorised as required and warrants have been issued.</p>																																																
2.	<p>Coordination and Planning</p> <p>Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.</p> <p>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.</p> <p>Risk-based priorities for official controls within the local area in 2015 were planned/scheduled in order to meet the standard rate of inspection set in <i>Guidance Note No. 1 (Revision 2)</i>. The review of the ten manufacturing establishment files by the audit team confirmed that they were inspected in line with the standard rate of inspection for their relevant risk category. A copy of the inspection targets for all food businesses and the number of inspections achieved for the local area for 2014 and 2013 was provided to the audit team and is outlined in Table 5. This target includes planned and planned surveillance inspections but does not include complaints and unplanned work. In general, the inspection targets were achieved in 2014, but not for Category 2 and 3 establishments in 2013. The audit team noted that in 2013, staffing levels were reduced by one whole time equivalent due to statutory leave (corresponding to 20% approx. of available staff for 2013) and activity supporting the introduction of the environmental health information system.</p> <p>Table 5: Clondalkin Local Area - Inspection achieved applying the standard rate of inspection set in Guidance Note 1 (Revision 2)</p> <table border="1" data-bbox="231 1232 1468 1724"> <thead> <tr> <th rowspan="2">Food Business Risk Category</th> <th colspan="3">2014</th> <th colspan="3">2013</th> </tr> <tr> <th>Number of inspections carried out/target number of inspections</th> <th>+/-</th> <th>% of target achieved</th> <th>Number of inspections carried out/target number of inspections</th> <th>+/-</th> <th>% of target achieved</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>16/16</td> <td>0</td> <td>100</td> <td>18/22</td> <td>+4</td> <td>122</td> </tr> <tr> <td>2</td> <td>44/46</td> <td>+2</td> <td>105</td> <td>42/30</td> <td>-12</td> <td>71</td> </tr> <tr> <td>3</td> <td>368/358</td> <td>-10</td> <td>97</td> <td>412/276</td> <td>-136</td> <td>67</td> </tr> <tr> <td>4</td> <td>96/124</td> <td>+28</td> <td>129</td> <td>83/86</td> <td>+3</td> <td>104</td> </tr> <tr> <td>5</td> <td>47/40</td> <td>-7</td> <td>85</td> <td>58/33</td> <td>-25</td> <td>57</td> </tr> </tbody> </table> <p>A review of the 'date of last inspection' for all food businesses in the local area identified all Category 1, 2 and 3 businesses had been inspected in either 2014 or 2015. Routine food sampling is planned in accordance with the <i>Risk-Based Guidance for Routine Microbiological Sampling</i> and the 2015 microbiological and chemical analysis sampling plans. A sampling rota is issued each quarter to facilitate this.</p>	Food Business Risk Category	2014			2013			Number of inspections carried out/target number of inspections	+/-	% of target achieved	Number of inspections carried out/target number of inspections	+/-	% of target achieved	1	16/16	0	100	18/22	+4	122	2	44/46	+2	105	42/30	-12	71	3	368/358	-10	97	412/276	-136	67	4	96/124	+28	129	83/86	+3	104	5	47/40	-7	85	58/33	-25	57
Food Business Risk Category	2014			2013																																													
	Number of inspections carried out/target number of inspections	+/-	% of target achieved	Number of inspections carried out/target number of inspections	+/-	% of target achieved																																											
1	16/16	0	100	18/22	+4	122																																											
2	44/46	+2	105	42/30	-12	71																																											
3	368/358	-10	97	412/276	-136	67																																											
4	96/124	+28	129	83/86	+3	104																																											
5	47/40	-7	85	58/33	-25	57																																											

	<p>All food businesses in the local area are on public water supplies. A water sampling plan is in place for 2015 which focuses on high-risk establishments such as hospitals and establishments that are approved under Regulation (EC) No 853/2004.</p>
<p>3.</p>	<p>Prioritisation of Official Controls and Risk Categorisation</p> <p>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.</p> <p>Routine inspection targets are set in <i>Guidance Note No.1 (Revision 2)</i>. The principal environmental health officer meets with the senior environmental health officer regularly to review targets and any issues arising.</p> <p>A priority action list is in place. In 2014, the target inspection rate was generally met for Category 1, 2, 3 and 4 premises. In 2013, the target inspection rate was not met for Category 2, 3 & 5 premises but was achieved for Categories 1 and 4. The audit team noted that in 2013, staffing levels were reduced by one whole time equivalent due to statutory leave (corresponding to 20% approx. of available staff for 2013) and activity supporting the introduction of the environmental health information system.</p> <p>Briefing sessions or all-staff information meetings are arranged regularly (approximately eight in 2014, three meetings held to-date in 2015). Targets are monitored when compiling returns as these results indicate if official controls are being carried out in line with the targets set in <i>Guidance Note No.1 (Revision 2)</i>.</p>
<p>4.</p>	<p>Documented Procedures</p> <p>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.</p> <p>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.</p> <p>The audit team verified that inspections are planned and are generally performed in accordance with <i>Guidance Note No.1 (Revision 2)</i>.</p> <p>In three cases, non-compliances identified on the visit record were not documented on the letter to the food business operator. A verbal report was issued in one of these cases.</p> <p>Routine microbiological sampling is carried in accordance with the <i>Risk Based Guidance for Routine Microbiological Sampling</i>. Chemical sampling is carried out according to the chemical sampling plan for the year. The sampling plans are reviewed in the office on an on-going basis and are adaptable to take into account changing resources, establishment profiles and risk-based priorities.</p> <p>A number of environmental health protocols/documented procedures were audited:</p> <ul style="list-style-type: none"> • Protocol 39 Calibration: The senior environmental health officer is responsible for organising the calibration of thermometers. All thermometers are sent for external calibration. Records reviewed indicated that thermometers were in calibration • Protocol 14 Export Certs: Exports certs reviewed are issued in line with procedures • Protocol 4 Complaints: Complaints reviewed were logged and closed off in line with procedures

5.	<p>Identification, Follow-up and Close-out of Non-compliances</p> <p>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.</p> <p>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.</p> <p>A review of ten food manufacturing establishment files by the audit team found that non-compliances identified during inspections are generally followed up as per the requirements of <i>Guidance Note No. 1 (Revision 2)</i>. However, the close-out of findings from previous inspections is not always documented on the file.</p> <p>On a number of files, non-compliances reported in the letters to food business operators were not documented in the visit record. In one file, a non-compliance identified with HACCP in a visit record was not reported in the letter to the food business operator. Similarly, in another establishment a non-compliance with QUID⁹ was identified on the visit record but not reported on the letter to the food business operator. Minor non-compliances were identified in one food manufacturing establishments but only verbal advice was given.</p> <p>For one of the manufacturing establishments visited by the audit team, the visit record for the most recent inspection was marked as compliant with regards to Regulation (EC) No 2073/2005 but the audit team identified significant non-compliances against this Regulation.</p> <p>In the two food manufacturing establishments visited by the audit team the following points were noted:</p> <ul style="list-style-type: none">• Establishment 1 (risk Category 1): Regulation (EC) No 2073/2005, HACCP and labelling non-compliances identified during the audit had not been identified during a recent official control inspection• Establishment 2 (risk Category 1): On the day of the audit, non-compliances were identified in relation to the application of HACCP procedures and Regulation (EC) No 2073/2005. Some but not all, of these non-compliances had been identified previously by official controls at the establishment
6.	<p>Reports to Food Business Operators</p> <p>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.</p> <p>The national protocol requires inspection reports to be issued when non-compliances are found. From the files reviewed, food business operators received a written report in the majority of cases where inspections identified non-compliances. However, in some instances, non-compliances identified in the visit record were not included on the letter to the food business operator.</p>

⁹ QUID stands for Quantitative Ingredient Declaration. In certain circumstances, it is necessary to state on the label the quantity, in percentage terms, of an ingredient or category of ingredients used in the manufacture or preparation of a foodstuff. The percentage quantity should be in or next to the name of the food or be in the list of ingredients.

7.	<p>Verification and Review of Official Controls and Procedures</p> <p>Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.</p> <p>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.</p> <p>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.</p> <p>Performance monitoring, i.e. the achievement of targets against the plan, and a review of official controls are carried out by the principal environmental health officer and senior environmental health officer within the local area. All-staff meetings take place where targets are discussed.</p> <p>The principal environmental health officer had recently introduced a desk-based audit using a standardised questionnaire, to audit food business operators' file to verify that official controls were being carried out consistently, and in line <i>Guidance Note No.1 (Revision 2)</i>. One file review has been completed. Prior to this, the principal environmental health officer undertook a file review only when enforcement action was being considered in an establishment.</p> <p>Joint inspections may also take place where the senior environmental health officer accompanies environmental health officers on difficult inspections, out-of-hours inspections, food poisoning investigations, etc. Evidence of these joint inspections was seen on the files.</p>
8.	<p>Staff Performing Official Controls</p> <p>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.</p> <p>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.</p> <p>Training in local offices is dependent on a national training plan which is developed annually. Staff interviewed during the audit were knowledgeable of the requirements of national and EU legislation requirements and also with <i>Guidance Note No.1 (Revision 2)</i> and Environmental Health Service protocols. An annual training needs assessment has been completed for Environmental Health Service staff and this returned for inclusion in the national training plan. The office recently completed the FSAI's online training programme on food contact materials as a group and reported that this greatly facilitated group discussion. The office plans to repeat this exercise with any new online training programmes that are issued, such as that on Regulation (EC) No 2073/2005.</p>

9.	<p>Coordination & Communication</p> <p>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.</p> <p>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.</p> <p>The audit team saw evidence of communication between national management (regional chief environmental health officer/national management team), the principal environmental health officer and the local team regarding targets and inspection numbers. Coordination of official controls within the local area and updates on official control activities are provided by staff at staff meetings. A number of staff in the office are members of national committees including food legislation, enforcement consistency and training. The audit team was provided with agendas and minutes of meetings that had taken place demonstrating that information from these national committees was being communicated and disseminated to environmental health staff in the local area.</p>
10.	<p>Registration and Approval</p> <p>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.</p> <p>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.</p> <p>The audit team confirmed that all of the ten manufacturing establishments for which files were reviewed were registered under Regulation (EC) No 852/2004. Three food manufacturing establishments were approved under Regulation (EC) No 853/2004. However, one of these establishments was visited by the audit team, who noted that while fish is processed on-site, this is not included on the approval certificate.</p>

Service Contract requirements

There was limited evidence of official controls in relation to food contact materials on the files¹⁰.

¹⁰ Training on food contact materials was undertaken in the office prior to the audit on the 4th June 2015."

4.7. Audit Findings ~ Local Area, Kerry

Official Control Audit Findings	
1	<p>Organisation and Structure of Official Controls</p> <p>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.</p> <p>Article 4(2) requires that the competent authorities ensure that:</p> <ul style="list-style-type: none"> • 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 <p>A structured approach for the organisation of staff for the performance of official controls was in place. The office is responsible for carrying out official controls in 2,479 food establishments (including 20 proposed establishments that are yet to be categorised). The current whole time equivalent for food control is approximately 14.45, including one principal environmental health officer, five senior environmental health officers and 12 environmental health officers.</p> <p>Responsibilities for delivery of the food control service is organised by the principal environmental health officer and the senior environmental health officers. In addition to the supervision of food businesses, senior environmental health officers supervise the five environmental health teams: three teams in Tralee and two in Killarney. The senior environmental health officers act as team lead and are responsible for monitoring local environmental health officers' targets and official control functions in those teams.</p> <p>Each environmental health officer/senior environmental health officer is responsible for supervising an allocated number of establishments and for conducting all official controls (including complaints, outbreaks, labelling, sampling plans etc.) related to those establishments.</p> <p>Cover for leave arrangements is organised within the senior environmental health officer teams by pairing arrangements. In addition, a rota is in place for reactive work if staff are on leave. One environmental health officer is currently on statutory leave.</p> <p>Specialist functions are allocated to some staff for duties relating to Regulation (EC) No 853/2004 approval, training, animal by-product, specified risk material, enforcement consistency, sampling etc.</p> <p>The local area confirmed it has adequate laboratory capacity for testing.</p> <p>Environmental health officers were authorised as required and warrants had been issued.</p>
2	<p>Coordination and Planning</p> <p>Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities.</p> <p>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.</p>

Audit of Official Controls in Manufacturing Establishments supervised by the Health Service Executive

SEPTEMBER 2016

Risk-based priorities for official controls within the local area in 2015 are planned/scheduled in order to meet the standard inspection target set in *Guidance Note No. 1 (Revision 2)*.

In the local area, a large number of the food businesses are seasonal, operating only from Easter to the end of August, and hence may receive the minimum standard of inspection; however, food manufacturing establishments tend to operate the year round.

A copy of the environmental health targets and the number of inspections achieved for all food businesses in the local area for 2014 and 2013 was provided to the audit team. This is outlined in Table 6. The target includes planned and planned surveillance inspections but not complaints and unplanned work.

The substantial difference between the number of establishments in 2013 (1,780) and 2014 (2,419) is due to B&Bs being risk categorised in 2014 (they were uncategorised in 2013). Inspection targets were met for Category 1 and almost achieved for risk Category 2 and 3 establishments in 2013 and 2014. Category 4 establishments were inspected well in excess of targets for both years. All risk Category 1 and 2 establishments and the majority of Category 3 establishments had received an inspection in 2014 or 2015.

Table 6: Kerry Local Area - Inspection achieved applying the standard rate of inspection set in Guidance Note No.1 (Revision 2)

Food Business Risk Category	2014			2013		
	Number of inspections carried out/target number of inspections	+/-	% of target achieved	Number of inspections carried out/target number of inspections	+/-	% of target achieved
1	6/6	0	100	8/8	0	100
2	246/223	-23	91	232/205	-27	88
3	957/854	-103	89	914/897	-17	98
4	421/609	+188	144	382/493	+111	129
5	214/169	-45	78	205/132	-73	64

Routine food sampling is planned accordance with the *Risk-Based Guidance for Routine Microbiological Sampling* and the 2015 microbiological and chemical analysis sampling plans. The local area has a sampling rota in place to facilitate this.

The office maintains a list of food establishments that use private wells, and forwards this list to the County Council, who then sample these private wells to check that the water supply complies with the drinking water legislation. The County Council informs the principal environmental health officer of any non-compliant results. As a double-check, the office also sets a target to sampling private wells once per year.

3.	<p>Prioritisation of Official Controls and Risk Categorisation</p> <p>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.</p> <p>Routine inspection targets are set in <i>Guidance Note No. 1 (Revision 2)</i>. The principal environmental health officer meets with the senior environmental health officer team approximately twice per year to review inspections, targets and to discuss official controls for the office. Targets are generally achieved (Table 6). The audit team reviewed ten files in the office and this provided evidence that in 2014/2015, manufacturers were regularly inspected in line with the standard rate of inspection for the relevant risk category.</p> <p>Performance monitoring, i.e. the achievement of targets against the plan, and a review of official controls are carried out by the senior environmental health officers every quarter. An activity sheet is completed by each environmental health officer and submitted to the senior environmental health officer. The senior environmental health officer forwards this to the principal environmental health officer. In addition, a file review is carried out and documented by the principal environmental health officer on two files per environmental health officer per year. A revised file review checklist was agreed by all staff in July 2015 and reviews will also be carried out by senior environmental health officers in 2015.</p> <p>A priority action list is in place. In the local area, a number of food businesses have remained on the priority action list since 2013 as a means of closely monitoring these food business operators.</p>
4.	<p>Documented Procedures</p> <p>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.</p> <p>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.</p> <p>The audit team verified that, in the local area, inspections are planned and are generally performed in accordance with <i>Guidance Note No. 1 (Revision 2)</i>. Routine microbiological sampling is carried out in accordance with the Risk-Based Guidance for Routine Microbiological Sampling. Chemical sampling is carried out according to the chemical sampling plan for the year. The sampling plans are reviewed in the office on an on-going basis and are adaptable/flexible to take into account changing resources, establishment profiles and risk-based priorities. Although this local area has set a target of sampling water once per year from food establishments that use private water supplies to check that it complies with the drinking water legislation, this was not achieved in 2013 and 2014. In addition, some water samples were only tested for microbiological parameters, not chemical parameters.</p> <p>The Environmental Health Service uses a standard template letter for reporting non-compliances identified during inspections to food business operators. The audit team observed that on three of the ten food manufacture files it reviewed, changes had been made to the template letters before they were issued to food business operators. In these cases, the food business operator had either been informed of the month of the next inspection (inspections should be unannounced) or non-compliances with the legislation were reported to the food business operator as recommendations. It was also noted that in two files, non-compliances recorded in visit records were not notified to the food business operators.</p>

	<p>It was noted by the audit team that one establishments classified as food manufacturers was supplying the final consumer only, i.e. therefore, it was a retail establishment</p> <p>A number of environmental health protocols/documented procedures were audited:</p> <ul style="list-style-type: none">• Protocol 39 Calibration: Calibration is organised in each office by an environmental health officer. All thermometers and equipment for calibration are sent externally once a year and are internally calibrated every six months. Thermometers were in calibration• Protocol 4 Complaints: Complaints were logged and closed out in line with procedures
5.	<p>Identification, Follow-up and Close-out of Non-compliances</p> <p>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.</p> <p>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.</p> <p>Non-compliances identified during manufacturer's inspections are generally followed up as per <i>Guidance Note No.1 (Revision 2)</i> and this was verified by the auditors on the ten food manufacturing establishment files reviewed. Findings from previous inspections are assessed for their close-out at the next inspection and this was documented on the files reviewed. Different systems of documenting close out of findings were in place, with some environmental health officers recording the close out of non-compliances on the visit record, and others recording it in their contemporaneous notes.</p> <p>In the file review it was noted that in two files, non-compliances recorded in visit records were not notified to the food business operators, so it was unclear if they had been followed up and closed out.</p> <p>In the two food manufacturing establishments audited:</p> <ul style="list-style-type: none">• Establishment 1 (risk Category 1): One inspection took place over two days, a number of days apart. On the first visit a number of non-compliances were identified on the visit record but were not notified to the food business operator in writing as, by the date of the second part of the inspection, the food business operator had closed out on the non-compliances which had been reported verbally at the first visit. A number of minor non-compliances were identified in relation to HACCP and some of these had not been identified by official controls at the establishment• Establishment 2 (risk Category 1): Non-compliances found by the audit team had previously been identified by official controls at the establishment but remain open

6.	<p>Reports to Food Business Operators</p> <p>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.</p> <p>The national protocol requires inspection reports to be issued when non-compliances are found. From the ten food manufacturing establishment files reviewed, the audit team confirmed that food business operators received a written report in the majority of cases where inspections identified non-compliances. On three files, an inspection which took place over two days was recorded on the environmental health information system as two inspections but only one letter was issued. In one case, non-compliances were not issued to the food business operator in writing as they had been closed out by the food business operator by the time the second visit for this inspection (a number of days later) was carried out.</p> <p>On two files reviewed, non-compliances were identified on the letter to the food business operator as recommendations, not as non-compliances.</p>
7.	<p>Verification and Review of Official Controls and Procedures</p> <p>Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.</p> <p>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.</p> <p>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.</p> <p>Performance monitoring, i.e. the achievement of targets against the plan, and a review of official controls is carried out by the principal environmental health officer and senior environmental health officers within the Kerry local area. Staff environmental health meetings, senior environmental health officer/environmental health meetings and senior environmental health officer/principal environmental health officer meetings take place where targets are discussed.</p> <p>The principal environmental health officer carries out a desk-based audit using a standardised questionnaire, on food establishment files to verify that official controls were being carried out consistently, and in line <i>Guidance Note No.1 (Revision 2)</i>. From July 2015, senior environmental health officers will also carry out file reviews using a standard template.</p> <p>Joint inspections may also take place where senior environmental health officer(s) and the principal environmental health officer accompany environmental health officers on difficult inspections, out-of-hours inspections, food poisoning investigations, etc. Evidence of these joint inspections was seen on the files.</p>

8.	<p>Staff Performing Official Controls</p> <p>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.</p> <p>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.</p> <p>Training in local offices 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 Guidance Note 1 (Revision 2) and environmental health service protocols. However, it was noted that on a number of files, the letters issued to food business operators included minor misinterpretations of the requirement of Regulation (EC) No 2073/2005, highlighting the need for more training in this area¹¹.</p> <p>Each year, staff complete a training needs assessment and this is returned for inclusion in the national training plan. In addition, day long all-staff meetings are arranged approximately twice every 12 months; these sessions now include a training component, e.g. Regulation (EC) No 2073/2005, HACCP, labelling etc.</p>
9.	<p>Coordination and Communication</p> <p>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.</p> <p>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.</p> <p>The audit team saw evidence of communication between national management), the principal environmental health officer and the local team regarding targets and inspection numbers.</p> <p>Coordination of official controls within the local area and updates on official control activities are provided by staff at staff meetings. A number of staff are members of nationally coordinated groups including animal by-products, HACCP group, food legislation and Regulation (EC) No 852/2004 review. The audit team was provided with agendas and minutes from meetings that had taken place, demonstrating that information was being communicated and disseminated to environmental health staff in the office.</p>

¹¹ The first module of the FSAI's online training programme on Regulation (EC) No 2073/2005 was launched in September 2015

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 audit team confirmed that all food manufacturing establishments for which files were reviewed were registered under Regulation (EC) No 852/2004.

In addition, one establishment was approved under Regulation (EC) No 853/2004. Another food establishment had completed the marginal, localised and restricted declaration form and was considered to have met the conditions required to avail of the derogation from approval.

However, the audit team did identify two establishments that should be considered for Regulation (EC) No 853/2004 approval. One of these was a food manufacturing establishment visited by the audit team. The food business operator had not been requested to complete a marginal, localised and restricted declaration form to avail of the derogation, if appropriate.

Service Contract requirements

Official controls in relation to non-hygiene legislation of the service contract were evident on the files.

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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