

AUDIT
REPORT

Audit of Official Controls
conducted by the Dairy
Produce Inspectorate in
Small Cheese Producing
Food Business Operations

Department of Agriculture, Food and
the Marine – Dairy Produce Inspectorate

FEBRUARY 2014



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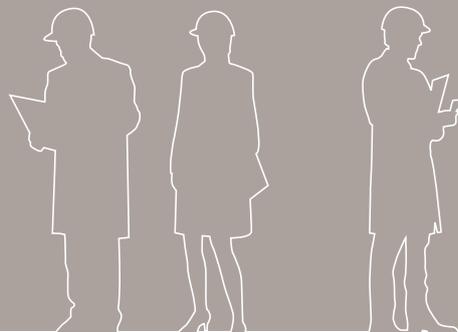


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1. GLOSSARY

DAFM	Department of Agriculture, Food and Marine
FSAI	Food Safety Authority of Ireland
FVO	Food and Veterinary Office
HACCP	Hazard Analysis Critical Control Point
SOP(s)	Standard Operating Procedure(s)

2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) has completed an audit of the official controls performed by the dairy produce inspectorate of the Department of Agriculture, Food and Marine (DAFM). The audit was undertaken as part of the planned programme of audits, carried out by the FSAI in 2013 to determine the level of compliance with Regulation (EC) No 882/2004 (official controls) and the service contract in place between DAFM and the FSAI.

The project included an audit of the four dairy produce inspectorate regions. The first part involved an audit of paperwork associated with official controls, including the establishment's files and inspection reports. The second part involved audits of two food business operations (small cheese manufacturers) in each dairy produce inspectorate region.

Official controls are carried out on a risk basis and at regular intervals in all regions. Agricultural inspectors and assistant agricultural inspectors carry out detailed inspections of the establishments and the food safety management systems based on HACCP, which are in place.

There are between 42-53 establishments approved by the dairy produce inspectorate in each region. The current number of dairy produce inspectorate staff is 28 which is the same number of staff as in 2010, although the distribution of staff amongst grades and between regions has changed. Official control inspections and sampling targets were not achieved in either 2011 or 2012. In the 2012 plan, 77% of inspections, 84% of food and environmental samples and 94.3% of water samples were completed. At the time of the audit, the Milk Hygiene Division was reapproving all dairy processing establishments and new approval certificates had been issued to all establishments audited.

The audit findings were largely positive in three of the four regions and the controls in place were effective. However, in one region audited, a number of issues were identified with the official control system in place including:

- The number of inspections completed and samples taken in small cheese manufacturers were below the planned number, 40.9% and 34% respectively
- The inspection frequency of the official controls was not planned in line with the risk rating of establishments and not in line with the agreed procedures
- Inspection of food safety management systems based on HACCP did not occur since 2010 in some establishments
- Food business operator sampling non-compliances found by the audit team during the audit were not identified
- The system of supervision as outlined in the dairy produce inspectorate Standard Operating Procedure (SOP 16) was not in place.

It was explained to the audit team that staff losses in this region were more severe than in other regions. However, this does not explain all of the issues found in the region. In addition, the ratio of food businesses to dairy produce inspectorate staff does not vary significantly across the regions.

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A comprehensive system of documented procedures is in place which outlines how the dairy produce inspectorate performs official control activities. Some weaknesses and gaps in the procedures were identified. Over the last number of years the major food safety issue of public health significance identified in small cheese manufacturers is the presence of *Listeria monocytogenes* in cheese. A review of two incidents per region showed that the dairy produce inspectorate took the precautions necessary to remove the affected cheese from the market in all cases. However, limited instructions for staff meant that different arrangements were put in place regarding testing of batches and positive release systems. The dairy produce inspectorate has met to discuss these issues with the intention of providing further guidance for inspectors.

Official Control Regulations require food inspectors to be kept up-to-date and receive regular training. Training for dairy produce inspectorates in local areas is dependent on national training. Staff interviewed during the audit were familiar with the requirements of food legislation and also with the dairy produce inspectorate's own SOPs. Nevertheless, the audit identified a requirement for further training in areas such as the microbiological criteria, labelling and additives.

General hygiene requirements relating to the design/layout, structure, equipment and facilities and HACCP were met in the establishments audited. Some deficiencies had been identified as requiring improvement/correction by the dairy produce inspectorate prior to this audit. However, other deficiencies in relation to the food business operators' sampling programmes were identified mainly in the South and South-East regions which had not been identified or closed out by the dairy produce inspectorate prior to the audit.

Systems are in place to verify the effectiveness of official controls at national and regional level. At national level, the inspectorate reports the planned and actual numbers of inspection and sampling activities to DAFM central management twice yearly. This allows for oversight of official control targets by DAFM central management of the output of the dairy produce inspectorate nationally. These data are also available in a regional format to regional agricultural inspectors and the senior inspector in charge of the inspectorate. In 2012, the dairy produce inspectorate introduced a SOP which outlines how official controls are to be monitored regionally and reported centrally, which when fully implemented in all regions, should lead to improved quality and consistency of official controls. At the time of the audit, this system of supervision was implemented in three of the four regions.

A review of the corrective action taken by the dairy produce inspectorate following two Food and Veterinary Office (FVO) missions (Meat/Milk and Microbiological Criteria) was carried out during this audit. Three findings are in progress and two are closed out for the 2011 meat/milk mission. Corrective action is on-going to close-out an observation on the microbiological criteria mission regarding the oversight of private laboratories by the inspectorate.

This report makes a number of findings requiring corrective action which, if implemented nationally, will enhance the effectiveness of official controls in small cheese manufacturing establishments.

3. INTRODUCTION

The FSAI is responsible for the enforcement of food legislation in Ireland. The FSAI carries out this enforcement function through service contracts with official agencies. These service contracts outline an agreed level and standard of food safety activity that the official agencies perform as agents of the FSAI. DAFM has entered into a service contract with the FSAI and is responsible for the enforcement of food legislation as it applies to dairy establishments including small cheese manufacturers. It is a requirement of the service contract and food legislation that DAFM ensures official controls are carried out regularly, on a risk basis, and with the appropriate frequency.

As part of its legal mandate, and in accordance with Schedule 5 of the Service Contract, the FSAI is required to verify that the system of official controls is working effectively. This audit was carried out for the purposes of assessing the official controls carried out by DAFM in small cheese manufacturers. Compliance by DAFM with relevant food legislation, adherence to the terms and requirements of the FSAI Service Contract, as well as conformance with relevant documented procedures, were assessed.

This audit was undertaken as part of the FSAI's audit programme for 2013. This report describes the audit objective, scope, methodology and the findings of the audit.

3.1 Audit Objective

The objective of this audit was to verify the delivery of official controls in small cheese manufacturers supervised by the DAFM dairy produce inspectorate. The audit focussed on the organisation, planning, coordination, delivery and review of official controls, related to the supervision of small cheese manufacturers.

In addition, the audit reviewed the action taken at national and regional level by the dairy produce inspectorate to address the findings, and recommendations from the FVO mission 2011-6017 'Official controls related to the safety of food of animal origin in particular meat and milk and their products' and the FVO mission 2011-6018 'Official controls on food safety and process hygiene criteria' (Commission Regulation (EC) No 2073/2005).

3.2 Audit Scope

FSAI audits of official controls involve verifying compliance by DAFM with regard to relevant legislation, adherence to the FSAI Service Contract and the official agencies own documented procedures (see Section 3.3 for the full range of audit criteria referred to as part of the audit).

The scope of the audit covered the implementation of official controls in small cheese manufacturers and the close-out of findings from the aforementioned 2011 FVO missions.

3.3 Audit Criteria and Reference Document

The audit criteria referred to during the audit included the following non exhaustive list:

- [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
- [Food Safety Authority of Ireland Act, 1998](#) (S.I. No. 29 of 1998)
- [Service Contract between FSAI and DAFM](#)
- [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,
- [Regulation \(EC\) No 854/2004](#) laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
- [Regulation \(EC\) No 2073/2005](#) on microbiological criteria for foodstuffs
- E.C. (Food and Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009)
- [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
- National Control Plan for Ireland 2012-2016
- Dairy produce inspectorate service plans and data supplied to the FSAI
- Dairy produce inspectorate documented procedures

3.4 Audit Methodology

This audit of official controls was undertaken using documented procedures which are included in the FSAI Quality Management System, namely the FSAI Audit Procedure. These procedures implement the FSAI audit obligations, defined in Schedule 5 of the Service Contract between the FSAI and DAFM, and in accordance with the requirements of Regulation (EC) No 882/2004 (including Annex Section 6.1 of Commission Decision 2006/677/EC) and also the FSAI Act.

An evaluation plan describing the audit process and approach (including the scope, objectives, criteria and the audit team) was sent to the DAFM dairy produce inspectorate ahead of the on-site activities. The evaluation plan also included a proposed audit itinerary with approximate timeframes for the completion of the audit. Following the issuing of the evaluation plan, the audit team also requested from the official agency their main procedure(s) used for the performance of official control duties at small cheese manufacturers. As part of the desktop element of this audit, a review of relevant information held within the FSAI was also carried out ahead of on-site activities. This included an evaluation of official controls and enforcement data received from DAFM and communicated principally in the form of returns to the FSAI as part of evidence of the official agency's delivery of the FSAI Service Contract requirements.

The audit included a review of the performance and delivery of official controls by the official agency at both DAFM central and regional levels. The audit team reviewed information and activities relevant to the supervision and performance of official controls at the establishment level and also regional results of official control audits and inspections carried out, sampling activities and analyses, as well as enforcement action(s) conducted.

The audit team evaluated whether the official controls were being carried out in accordance with DAFM's own documented procedures which are used to implement the service contract requirements with the FSAI.

As part of the audit of the food business operators, the audit team assessed the performance of the controls put in place at establishment level in relation to the implementation of good hygiene practices and principles of HACCP as part of the food business operator's food safety management system, sampling programmes and whether these were effective, adequately maintained and in compliance with food law.

On completion of the visits to establishments, the audit findings relevant to the food business operator were delivered by the FSAI audit team. The food business operator was informed that follow-up in relation to these would be carried out by DAFM and that the FSAI would communicate the audit findings to DAFM following completion of the audit. Following completion of all regional audits, a final closing meeting was also held with DAFM staff at central level where findings were discussed in order to allow follow-up in relation to any issues identified. In addition, preliminary findings were issued separately to each region.

4. AUDIT FINDINGS

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

4.1.1 Organisation and Structure of Official Controls

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

Findings

The dairy produce inspectorate is part of the DAFM agricultural inspectorate and is responsible for carrying out official controls in milk processing establishments including small cheese manufacturers. The dairy produce inspectorate operates on a regional structure, with four regions reporting to a senior inspector. In each region, an agricultural inspector manages the activities of assistant agricultural inspectors who are responsible for the day to day implementation of official controls in dairy establishments. Other staff, technical agriculture officers, senior dairy produce officers and dairy produce officers carry out ancillary functions such as sampling, market controls etc. In addition to the planned official control activities, the inspectorate also carries out reactive/unplanned controls.

Table 1 provides an overview of the number of establishments approved by region as well as the current 2013 staff breakdown. Nationally, the numbers of staff have not changed significantly since 2010 (Table 1). However, the type of staff employed has changed. There are now more assistant agricultural inspector grades employed and less auxiliary staff. The number of agricultural inspectors carrying out inspections in the South office is two full-time and one part-time, i.e. one assistant agriculture inspectors works four days in the laboratory and one day carrying out official controls at approved establishments. It is planned this assistant agriculture inspector will be full-time carrying out official controls at approved establishments by the end of 2013.

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Table 1: Overview of Approved Establishment Numbers and Staff Numbers by Region 2013*

Region	Mid-West	South East	South	North West	Total #
No of Establishments	53	40	49	46	188
Agricultural Inspector	1(1)	1(1)	1(1)	1(1)	4(4)
Assistant Agricultural Inspector	4(3)	2(2)	3*(2)	4(3)	13*(10)
Dairy Produce Officer	1(2)	1(2)	1(2)	0(1)	3(7)
Senior Dairy Produce Officer		(1)	(1)	1(1)	1(3)
Technical Agricultural Officer	2(1)	1(1)	2(1)	2(2)	7(5)
Total	8(7)	5(7)	7(7)	8(8)	28(29)

***Source:** Milk Hygiene Division, 3* assistant agricultural inspector in South in 2013 should be 2.25 – 1 assistant agricultural inspector part-time on field duties and part-time in Cork Dairy Science Lab.

*Staff numbers for 2010 are shown in brackets.

Official control activities are planned annually by the assistant agricultural inspector in conjunction with the agricultural inspector. Inspection and sampling targets are agreed in each region and forwarded to central management and the dairy science laboratories. Table 2 shows the % of planned official control activity achieved in 2011 and 2012. The audit team noted that planned targets for inspection, official control sampling and official water sampling were not met in either 2011 or 2012. A regional breakdown of official control plans and targets achieved is provided in Section 4.2.

Table 2: Percentage of Planned Official Control Plan Achieved in 2011 and 2012*

Official Control Activity	% of plan achieved	
	2011	2012
Inspections of Milk Processing Plants and Laboratory Checks	76%	77%
Sampling Controls for Food Safety, Process Hygiene, Antibiotics and Heat Treatment	79%	84%
Samples of Water under Directive 98/83	83%	94.3%

* **Source:** Data from MANCP Annual report 2011 and 2012

4.1.2 Coordination and Planning of Official Controls¹

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities. Article 4(5) of the Regulation requires that when, within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Findings

In terms of planning and coordination of official controls, the audit team confirmed that there was a structured and well organised approach for the prioritisation, planning, coordination and delivery of official controls between DAFM central and regional levels. Annually, the senior inspector in consultation with the regions, produces a business plan, which reflects the requirements of the inspectorates documented procedures for official control activities. The audit team confirmed that delivery of requirements are reviewed by the senior management of DAFM twice annually at MANCP meetings. These updates provide senior management with national figures but do not discuss regional variations.

Regional official control activities are planned and scheduled in accordance with the requirements of SOP 24 where an annual risk assessment is carried out in order to determine the frequency of visits to each establishment. In addition to agreeing targets and planning official controls, sampling plans are drawn up locally in conjunction with the regional agricultural inspector as per SOP 1. The audit team noted that agricultural inspectors in three out of four regions, were monitoring how official activities are carried out via SOP 16.

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

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

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Communication between national management and the regions in relation to the development and roll out of SOPs and updates on official control activities is provided. Formal meetings do not take place locally in the regions. However, there is regular communication between the agricultural inspector and the assistant agricultural inspector, and this was demonstrated during discussion by the agricultural inspector's familiarity with non-compliances and food business operator's files.

Table 3 sets down by region the number of planned versus actual official control inspections. All regions except the South exceed 80% of their planned activities. It was explained to the audit team that staff losses in the South region were more severe than in other regions². However, the audit team noted that the ratio of food business operators to dairy produce inspectorate staff does not vary significantly by region. Additionally, the Mid-West and North-West regions performed significantly more reactive official controls than the South and the South-East.

Table 3: Planned Official Control Inspections and Actual Inspection Carried out by Region*

Official Control Activity	Mid-West	South-East	South	North-West
Planned Official Controls	77	64	62	53
Actual Official Controls Performed and Percentage of plan completed	71 (92%)	63 (98%)	27 (43.5%)	43 (81.1%)
Reactive Official Controls	110	86	26	27

*Source: CR3, 2012

4.1.3 Approval of Establishments

Article 31 of Regulation (EC) No 882/2004 requires *Member States to establish procedures for the registration/approval of food and feed business establishments, for reviewing compliance with conditions of approval and for the withdrawal of approvals*

Article 4 of Regulation (EC) No 853/2004 requires that *establishments handling products of animal origin shall not operate unless the competent authority has approved them*

Findings

The Milk Hygiene Division of DAFM has a documented procedure, SOP 15, in place to process the approval and registration of food business operators. A list of registered and approved establishments under the supervision of the dairy produce inspectorate is available on DAFM's website. During the audit at central level, the audit team reviewed food business operator files to verify the approval process. In all files reviewed, approval had been granted in accordance with the requirements of Regulation (EC) No 853/2004.

² Since January 2014 the number of dairy produce inspectors in the South region has increased.

All premises audited had approval certificates in place which reflected the activities in the establishments. In 2012, the Milk Hygiene Division of DAFM commenced a process of reapproving all establishments under the supervision of the dairy produce inspectorate. The new approval certificates list the activities the establishments are approved for and also if relevant the certificate specifically states that authorisation does not extend to the manufacture and sale of raw products. In all of the establishments audited, new approval certificates were issued in recent months, although the process was not completed nationally for all small cheese manufacturing establishments at the time of the audit.

4.1.4 Prioritisation of Official Controls and Risk Categorisation

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

SOP 24 Rev 3 Section 2.3.1 'Official Control Plan' states that *in establishing the frequency of planned official controls, each establishment must be assessed annually by applying the rating scheme in Appendix V. The Official Control Plan excludes Reactive Controls. This risk rating shall determine the frequency of official controls and remain in place until circumstances change. In a multi facility site, a separate risk rating shall be carried out for each production unit and recorded on Form CR4.*

Findings

The risk rating for each establishment is assessed annually by the assistant agricultural inspector in conjunction with the agricultural inspector so as to determine the frequency of planned official controls. This process is laid down in SOP 24. A risk assessment had been carried out in all small cheese manufacturers to determine the nature and frequency of official controls to be performed. Records of the risk assessments carried out were available on the establishment files, maintained by the agricultural inspector or the assistant agricultural inspector.

The proportion of small cheese manufacturers allocated a high-risk rating is significantly lower in the South than in other regions (Table 4). Official control inspections had been carried out in all small cheese manufacturers during 2011 and 2012, except in a number of South region establishments. In the Southern region, these establishments did not have the appropriate inspection frequency allocated as per the risk rating in the SOP 24, e.g. in one establishment, the risk score was 55 and the planned inspection frequency was two per year, whereas in another establishment with a risk rating of 70, the inspection frequency was one.

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Table 4: Numbers of Small Cheese Manufacturers and Risk Categorisation by Region*

	South	South East	Mid-West	North West
No of Small Cheese Manufacturers	16	11	12	6
Risk Categorisation	15 Medium 1 High	8 Medium 3 High	5 Medium 6 High 1 not allocated (new establishment)	3 Medium 3 High
% of Small Cheese Manufacturers Allocated High-risk	6%	27%	50%	50%

*Source: Establishment list is provided by DAFM – Milk Hygiene Division for the audit

4.1.5 Documented Procedures

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

Findings

The dairy produce inspectorate has developed a comprehensive series of SOPs which describe how official controls are carried out. SOPs are developed by the agricultural inspectorate with responsibility for internal controls, in conjunction with agricultural inspectors and other staff. Special memoranda are also issued to staff in the event of issues arising following meetings etc.

The main official control tasks performed by agricultural inspectors at small cheese manufacturing establishments include inspections under SOP 24 and sampling under SOP 1. SOP 16 has been established to provide a supervisory system for the agricultural inspector and the assistant agricultural inspector in the region to assess the effectiveness of official controls and to enhance the system of oversight and supervision at regional and national level. SOP 16 has been implemented in three of the four regions. Regular inspections were carried out by DAFM at the eight food business operator establishments visited by the audit team.

The audit team confirmed that in general, the appropriate checks on structure, HACCP, sampling programmes etc. were being carried out by the agricultural inspectors in accordance with the requirements of Regulations and the SOPs. However, in a small number of cases, specific deficiencies were observed by the audit team in relation to the following:

Use of Checklists and Forms

There was evidence that the appropriate checklist or forms were not always used, including:

- CR2 (notification of an audit) are issued very infrequently
- CNs (Compliance Notice) not lifted with a CN4 form as per Appendix VII SOP 24
- Checklists A and B marked in a CR1 form not completed or the CR1 form was not available
- In most cases, the time frames for remedying corrective action were included on the CN reports. However, in a number of examples chosen, this was not always the case

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During the last FSAI audit of the dairy produce inspectorate in 2011, the dairy inspectorate committed to issuing a special memorandum setting down time guidelines for which all relevant checklists should be completed in an establishment. This memorandum had not been issued at the time of this audit³.

Food Safety Management System incorporating HACCP

The audit team confirmed that audits of food business operator food safety management system procedures incorporating HACCP had been carried out by the dairy produce inspectorate at six of the eight establishments visited by the audit team. The audit team noted that, in general, verification of food business operator own checks and monitoring of critical control points (CCPs) was being carried out comprehensively and at the required frequency by the dairy produce inspectorate. However, in the South region, a HACCP official control, i.e. Checklist D had not been carried out in a number of establishments since 2010.

SOP 1: Official Control Sampling and Reporting Procedures

The audit team noted a number of issues in relation to the SOP 1:

- Section 3.3 of SOP 1 states that *the criteria for what constitutes a batch shall be agreed between the manufacturer and the local Inspector*. It is the responsibility of the food business operator to describe and document their batch. **Related Finding:** *There is no prompt for the dairy produce inspectorate Inspector to check the definition of 'Batch' in the SOP checklists*
- There are limited instructions for dairy produce inspectorate staff regarding inspecting shelf-life (three of the eight food business operators audited had not undertaken shelf-life studies and this was not identified in the reports to food business operators)
- There are limited instructions for staff outlining the actions to be taken when *Listeria monocytogenes* is identified in cheese (see 4.6 findings below)

Non-hygiene Areas of the Service Contract

There are very few instructions for the inspectorate in relation to official controls of the non-hygiene legislation of the service contract, e.g. additives, labelling, food contact materials etc. Work however, has commenced at national level to review the legal requirements for food business operators in relation to the non-hygiene legislation and the subsequent implications for official control in the dairy produce inspectorate approved establishments.

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 and that the documentation referred to in paragraph 1 is updated as appropriate.*

³ SM 8 of 2013 was issued by DAFM on the 24/5/13

Findings

The official control inspections in three of the four regions are identifying and closing out the majority of non-compliances in food safety management systems, sampling and pre-requisite programmes in the food business operators audited. However, in the South region, the official controls did not identify a significant number of the non-compliances that the audit team identified, e.g. a number of issues regarding two food business operators' HACCP systems. Checklist D (Official Control of HACCP procedures) had not been completed by the dairy produce inspectorate since 2010 in either of the two food business operators audited.

In the Mid-West region in one establishment audited, hygiene issues identified by the dairy produce inspectorate at previous inspections, continue to reoccur at the establishment. As such, the audit team concluded that the action taken by the dairy produce inspectorate was not effective.

Although water pooling was identified in an inspection report in 2012, in a subsequent April 2013 report, floor surface and ventilation were assessed as being compliant. The audit team concluded that non-compliances in relation to pooling and ventilation were still present on the day of the FSAI audit⁴.

In the establishments in the South and South-East regions, the audit team noted that official controls are not identifying/documenting sampling and testing non-compliances in relation to Regulation 2073/2005, e.g. in relation to n=5.

To assess the action taken by DAFM at establishments following the detection of non-compliances relating to *L. monocytogenes* during the audit, two incidents were reviewed per region by the audit team. In general, the audit team was satisfied that a system was in place to ensure that cheese that tested positive for *L. monocytogenes* was withdrawn/recalled from the market. However, different arrangements were agreed locally for further testing of other batches of cheese, removal of product and the implementation of positive release systems. In one establishment in the North-West region, there are continuing *L. monocytogenes* issues, i.e. as identified in inspection reports that are not being closed out by the food business operator. Routine action is being taken by the dairy produce inspectorate as issues arise. The food business operator is currently operating on a positive release system. Procedures to deal with repeat or on-going *L. monocytogenes* non-compliances are subject to national review with dairy produce inspectorate management. A meeting has taken place to discuss the issues although at the time of the audit, these issues were still under review.

4.1.7 Reports to Food Business Operators and Announcing Inspections

Article 9 of Regulation (EC) No 882/2004 requires that *competent authorities to 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.*

dairy produce inspectorate SOP 24 Sections 3 states that *inspections shall be unannounced, whereas audits should be prearranged with the food business operator.*

⁴ Since the audit, the food business operator has closed out the non-compliances relating to floor surface damage.

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Copies of inspection reports were available for all establishments audited. In the files audited, the food business operators received a report after all inspections. In general, small cheese manufacturers are not receiving unannounced inspections; food business operators are generally contacted to ensure availability. There is no system in place for tracking unannounced inspections when they do occur.

4.1.8 Verification and Review of Official Controls and Procedures

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

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

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

Findings

In order to enhance the system of oversight and supervision at regional and national level, SOP 16 was introduced in 2012 and has been amended once since its introduction. The SOP provides for a:

- Desktop review of official controls, i.e. file review by the agricultural inspector
- Accompanied on the spot supervisory checks by the agricultural inspector
- Reporting arrangements regarding supervision to central level
- Joint assistant agricultural inspector controls

The regional agricultural inspector must complete annually, a plan that details the expected controls that will be carried out under SOP 16 and report the supervision that takes place to national management. SOP 16 is in operation in all regions except the south. Targets are monitored nationally via MANCP returns. However, national returns do not highlight regional variations. The percentage of planned official controls (inspection) achieved in small cheese manufacturers in the South region is significantly lower than in the other three regions.

Table 5: Official Control Inspection in Small Cheese Producers*

Official Control Activity	Mid-West	North-West	South	South-East
Planned Official Controls	16	9	22	14
Actual Official Controls Performed and Percentage Completed	15 (93.8%)	9(100%)	9 (40.9%)	13 (92.9%)
Reactive Official Controls	23	14	11	5

*Source: CR3/2012

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Sampling targets are monitored individually by agricultural inspectors, in some cases by the regional agricultural inspectors and nationally by the laboratories. Nationally in 2012, the dairy produce inspectorate achieved 69.5% of the targeted samples planned under SOP 1. The South region is well below the national average in achieving the targeted sampling numbers laid down in its sampling plan.

Table 6: Official Control Sampling by the Dairy Produce Inspectorate*

Official Control Activity	Mid-West	North-West	South	South-East
Total Food Safety Samples	1770 (81%)	970 (83%)	274 (43%)	655 (79%)
Total Process Hygiene Samples	1040 (86%)	605 (71%)	185 (31%)	415 (66%)
Total Samples as per SOP1	2548 (71%)	1705 (76%)**	459 (34%)	1111 (71%)

*Source: SP1 adjusted figures, 2012

Values in brackets are as a percentage of targets rounded to the nearest whole number.

**Information from the North-West region after the audit confirmed 98% of achievable targets for sampling were achieved, e.g. samples could not be taken where a premises was closed.

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

The audit team noted that the senior inspector forwards an annual training needs request to each of the regions and responses are then collated and forwarded to the DAFM training unit for the development of an annual training plan. Training is organised nationally and rolled out to the regions. Training records are maintained for each member of staff centrally. The audit team noted that HACCP training was organised for the inspectorate in early 2013 and staff attended numerous conferences/seminars and Better Training for Safer Food courses in 2012.

Authorisations to carry out official control activities under food legislation are in place for the agricultural inspectors and assistant agricultural inspectors. The agricultural inspector has a coordinating role in relation to oversight of assistant agricultural inspectors and technical staff work, which is generally organised at central level. The audit team noted that dairy produce inspectorate staff interviewed during the audit were knowledgeable of national and EU legislation requirements and also of dairy produce inspectorate SOPs. However, a number of non-compliances identified by the audit team in food business operators visited during the audit, highlighted a requirement for further training in specific areas to ensure staff are kept up to date in their areas of competence. In particular, further training should focus on:

- Regulation 2073/2005 on Microbiological Criteria
- Official controls in relation to non-hygiene legislation of the current service contract, e.g. labelling, controls on additives etc

4.2 Official Controls Performed in Food Establishments

As part of the audit of the food business operations, the audit team assessed the performance of the controls put in place at the establishments audited in relation to the implementation of good hygiene practices and principles of HACCP as part of the food business operator's food safety management system and whether these were being adequately maintained and were effective.

An assessment was made under (a) Structure, Maintenance & Operational Hygiene (b) Food Safety Management System (FSMS) and (c) Sampling and Testing.

Findings

Structure, Maintenance & Operational Hygiene

Articles 4(2) of Regulation (EC) No 852/2004 requires *food business operators to comply with general hygiene requirements as set out in Annex II of the Regulation. These provisions relate to cleaning and maintenance, layout, design, construction and size of food premises.*

The general hygiene requirements relating to the design/layout, structure, equipment and facilities were generally met in the establishments audited. The audit team noted that the majority of identified deficiencies in general hygiene requirements had been identified as requiring improvement or correction by the dairy produce inspectorate prior to this audit. In one establishment audited, there were on-going hygiene issues and some structural issues which were identified in an inspection report but are not being closed out by the food business operator. Since the audit, commitments have been provided by management to review and improve the identified deficiencies requirements by the audit team at this establishment.

Food Safety Management System

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

A documented food safety management system based on the principles of HACCP (including procedures and records) was in place in all of the establishments audited. Regular official control inspections identifying non-compliances were taking place in three of the four regions. In the South region, HACCP checklists had not been completed in some establishments since 2010. In the establishments audited by the audit team, some minor issues were identified with the systems in place, including:

- In three establishments, the food business operator's food safety management systems were not entirely up-to-date/reflective of current operations
- In three establishments, there were shortcomings in relation to calibration of equipment
- In the one establishment in the South region, the food safety management system was not sufficiently documented in relation to hazard analysis and monitoring of CCPs

Sampling and Testing: Regulation 2073/2005

Sampling programmes were in place in all the establishments audited and in general, there was a good level of compliance with the Regulation. Five of the eight food business operators audited were following the sampling plan outlined in Annex I of the Regulation, i.e. n=5, for *L. monocytogenes*, two were not following the sampling plan and one was about to commence following the sampling plan.

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A 'batch' was defined in each of the establishments audited. Three food business operators had not undertaken shelf- life studies. Food business operators in all establishments audited were taking environmental swabs although two of the smaller scale food business operators were not trending their sample results. However, the audit team noted that these food business operators were reviewing their results.

Sampling and Testing: Water

Compliance with the requirements of S.I. No. 278 of 2007 [European Communities (Drinking Water) (No. 2) Regulations, 2007] was more varied. Microbiological analysis of water was taking place in six of the eight establishments audited but not necessarily for all microbiological parameters as required. The audit team noted that there was limited chemical sampling taking place in three of the eight establishments. The audit team noted that the requirements for food business operator water sampling are subject to on-going national review by the official agencies and the FSAI.

Sampling and Testing: Laboratories

The audit team noted that the agricultural inspectors do not approve in-house or private laboratories that carry out sampling for food business operators. A questionnaire has been sent to all private laboratories by DAFM's Dairy Science Laboratory in Backweston Dublin, to review the tests and methods used by the dairy industry. Much of these data have been gathered and are currently being reviewed. The audit team was informed by the dairy produce inspectorate that when this review is completed an SOP will be developed for the dairy produce inspectorate to outline the legal requirements for food business operator sampling and testing.

5. REVIEW OF PREVIOUS FVO MISSIONS TO IRELAND

During this audit, a review of the audit findings of two previous FVO missions to Ireland was carried out by the audit team, i.e. 6017 - Meat /Milk and 6018 - Microbiological Criteria. The audit team noted that three findings are currently in progress and two are closed out, i.e. see Annex 1. In addition, corrective action to address an observation found during the microbiological criteria mission in 2011 regarding the supervision of private laboratories is still in progress. As previously mentioned, the DAFM Dairy Science laboratory in Backweston, Dublin in conjunction with the dairy produce inspectorate, is gathering data regarding private laboratory testing.

6. CONCLUSIONS

The audit team confirmed that there was a well organised and structured approach for the prioritisation, planning, coordination and delivery of official controls between DAFM central and regional levels within the dairy produce inspectorate. Whilst in general, official controls were being carried out satisfactorily at the establishments visited, staff numbers were not able to achieve the targets set for official controls at establishment level, particularly in the South region.

The audit team found evidence that procedures were being more strictly followed in three of the four regions regarding inspection tasks carried out, demonstrating a variation in consistency and effectiveness of official controls between the regions.

The audit team noted that in general, detailed food safety management systems had been put in place by the food business operators at each of the establishments audited in order to comply with the requirements of Article 5 of Regulation (EC) No 853/2004. Although generally in compliance, the audit team noted a number of opportunities

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for improvement in particular in relation to sampling which were highlighted during the course of the audit. In one establishment audited in particular, structural and maintenance deficiencies were observed which did not fully comply with the requirements of Regulations 852/2004 and 853/2004. Many of these had also been highlighted in previous DAFM audits of this establishment. Following the FSAI audit, correspondence was provided by DAFM of corrective actions taken to remedy deficiencies highlighted at the food business operator establishments audited.

DAFM is in the process of agreeing a procedure to manage effectively the close out of repeat *L. monocytogenes* positives in small cheese manufacturers.

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.

7. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION

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.

Audit findings requiring corrective action are listed in the corrective action plan.

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Annex 1

Finding	FVO Assessment	Update	FSAI Assessment
To ensure that the approval of establishments is kept under review when carrying out official controls as required by Article 31.2(e) of Regulation (EC) No 882/2004	DAFM dairy produce inspectorate Dairy Controls & Certification Division will review its procedures and amend where appropriate to ensure that the approval of establishments is kept under review when carrying out official controls as required by Article 31.2(e) of Regulation (EC) No 882/2004	<i>Mid 2012 DAFM Milk Hygiene Division commenced a process of re approving all milk product establishments. Approvals are now granted for the food business operator activities and not products produced. Evidence of new approval certificates was seen by the audit team in the establishments audited. It is not planned to carry out a physical re approval ensuring an establishment is complying with its approval is part of on-going official controls.</i>	In Progress All establishments have yet to be reapproved. Onsite re-approvals are part of on-going dairy produce inspectorate supervision in establishments. However, the checklists do not specifically document that an establishment approval has been reviewed.
To ensure that official controls are effective and appropriate action is taken in case of non-compliances, as required by Articles 4.2 and Article 54 of Regulation (EC) No 882/2004	DAFM dairy produce inspectorate By end of quarter 2 of 2012, Dairy Controls & Certification Division will review and amend its procedures where appropriate, to ensure that official controls are effective and appropriate action is taken in case of non-compliances, as required by Articles 4.2 and Article 54 of Regulation (EC) No 882/2004. DAFM dairy produce inspectorate A working group has been established and some preliminary work done, a timescale of two months starting June 2012 has been allocated for this. Document provided.	<i>A system of supervision via SOP 16 is now being implemented in 3 of the 4 regions.</i>	In Progress One region has still to implement new procedure.
To ensure that the HACCP-based systems in meat and milk establishments are in line with Article 5 of Regulation (EC) No 852/2004	DAFM dairy produce inspectorate As part of Dairy Controls & Certification Division process of continuing improvement, officers will receive planned refresher training on procedures based on HACCP principles in 2012, to ensure that the HACCP-based systems in milk processing establishments are in line with Article 5 of Regulation (EC) No 852/2004.	<i>HACCP training was provided in March 2013.</i>	In Progress HACCP-based procedures were in place in all establishments audited. In the South, HACCP checklists had not been completed in some establishments since 2010.

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Finding	FVO Assessment	Update	FSAI Assessment
<p>To ensure that the requirements of Chapter I, Section IX, Annex III to Regulation (EC) 853/2004 in relation to the use of raw milk from animals not complying with the requirements of points 1 to 3 of Chapter I, Section IX, Annex III to Regulation (EC) 853/2004, and, in particular, from any animals showing a positive reaction to the prophylactic test vis-à-vis TB, are met.</p>	<p>DAFM dairy produce inspectorate DAFM procedures to be amended (by end of quarter 2 of 2012) to include controls to ensure that the requirements of Chapter I, Section IX, Annex III to Regulation (EC) 853/2004 in relation to the use of raw milk from animals not complying with the requirements of points 1 to 3 of Chapter I, Section IX, Annex III to Regulation (EC) 853/2004, and, in particular, from any animals showing a positive reaction to the prophylactic test vis-à-vis TB, are met</p> <p>Draft checklist provided amending current Dairy Controls & Certificate Division controls. Revised checklist and SOP to be issued by end of Q2.</p>	<p><i>SOP 23 and related documents on official controls on food business operators producing and/or collecting raw milk has been amended. The term inconclusive is now clarified in Annex IV.</i></p> <p><i>Information on milk suppliers and the health status of herds was included on establishments files audited.</i></p>	<p>Closed</p>
<p>To ensure effective co-ordination between the different units of the same competent authority responsible for official controls at establishment and holding levels in case of TB breakdowns, as required by Article 4(5) of Regulation (EC)</p>	<p>A formal system of communication between the relevant divisions of DAFM will be established (by end of quarter 1 of 2012) in the cases of TB breakdowns, as required by Article 4(5) of Regulation (EC) No 882/2004.</p> <p>DAFM circular provided - notifying milk purchaser of herd restriction and de-restriction and new DAFM procedures ER 122A and ER 122B forms.</p>	<p><i>Circular sent by ERAD to regional offices informing them of revised arrangements to inform milk purchasers and assistant agricultural assistant/ regional agricultural assistant when restriction and removal of restrictions take place following a TB positive.</i></p>	<p>Closed</p>

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FVO Mission to Evaluate the Official Controls on Food Safety and Process Hygiene Criteria (Commission Regulation (EC) No 2073/2005)

Observation	Update	FSAI Assessment
<p>As regards the dairy inspectorates (April 2011) and the Sea-Fisheries Protection Authority's supervision of 13 private laboratories (2009), special questionnaires have been elaborated to collate information on the use of private laboratories to ensure compliance. The use of questionnaires is only being implemented as regards dairy controls (so far a quarter of the questionnaires have been evaluated).</p>	<p><i>Evaluation of private laboratories is being carried out by the Dublin Dairy Science laboratory in conjunction with regional agricultural inspectors and assistant agricultural inspectors to review tests performed and methods used by private laboratories for milk product analyses by the industry. This project was on-going at the time of the audit. This evaluation is in progress since 2011.</i></p>	<p>In Progress</p>
<p>In one of two dairy establishments visited producing cheeses, the DAFM dairy inspectorate was not able to provide documentation for the controls over the food business operators' sampling and testing for food safety criteria.</p>		



Abbey Court,
Lower Abbey Street,
Dublin 1.

Advice Line: 1890 336677
Telephone: +353 1 817 1300
Facsimile: +353 1 817 1301
Email: info@fsai.ie
Website: www.fsai.ie