

AUDIT  
REPORT

Audit of Compliance  
of Official Food Microbiology  
Laboratories with Regulation  
(EC) No 882/2004 and  
Service Contract Obligations  
– Health Service Executive

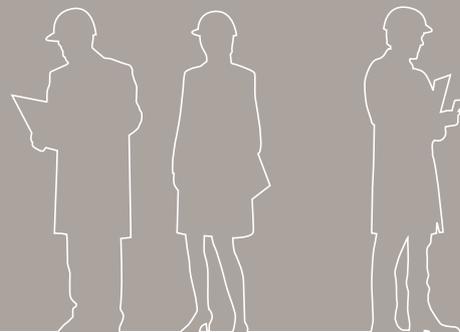
NOVEMBER 2015



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## **1. GLOSSARY**

DAFM	Department of Agriculture, Food and the Marine
EHO	Environmental Health Officer
FSAI	Food Safety Authority of Ireland
FVO	Food and Veterinary Office
HSE	Health Service Executive
INAB	Irish National Accreditation Board
NSAI	National Standards Authority of Ireland

## **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.

The FSAI completed an audit of the Health Service Executive (HSE) Official Food Microbiology Laboratories and their compliance with Regulation (EC) No 882/2004 and FSAI Service Contract obligations, i.e. for the purposes of assessing the delivery of official controls performed. Seven Official Food Microbiology Laboratories perform microbiological analysis as part of the HSE Food Safety Laboratory Service. One Official Food Microbiology Laboratory is also an integral part of the Public Analyst Laboratory service, while the other six microbiology laboratories operate independently as public health laboratories within the HSE, some of which are attached to hospitals and perform clinical testing.

A detailed pre-audit questionnaire was sent to each Official Food Microbiology Laboratory and these were completed and returned to the FSAI audit team. Three out of the seven Official Food Microbiology Laboratories were selected for the on-site audit activities. These were chosen randomly as no significant differences were observed between seven laboratories, i.e. when comparing the results of the pre-audit questionnaires received.

During the audit, the FSAI team required evidence that the relevant aspects of legislation and FSAI Service Contract requirements were being fulfilled and the FSAI audit team did not presume that these were automatically fulfilled by the laboratories accreditation to ISO 17025. Following the audit in each Official Food Microbiology Laboratory, a report of preliminary audit findings was sent to each of the laboratories visited.

In general, a structured approach to the planning, coordination and delivery of official controls was verified as being in place in the three Official Food Microbiology Laboratories visited.

In general, an effective system of official controls was in place each of the Official Food Microbiology Laboratories audited for microbiological testing/analysis and reporting performed, i.e. subject to a number of findings identified in this report that require corrective action to be taken.

An effective system of official controls was demonstrated in each of the three Official Food Microbiology Laboratories audited, principally via:

- Their satisfactory performance in ongoing internal and external quality assurance checks conducted, i.e. internal quality assurance and external quality assurance, including proficiency testing and associated results
- Internal audits performed in the Official Food Microbiology Laboratories with effective follow-up and clearance of non-conformities identified
- Coordination of official control laboratory activities and the ongoing monitoring and review of performance
- Delivery of microbiological testing requirements as part of the annual Environmental Health Service sampling programmes for 2013 and 2014
- The ongoing maintenance of laboratory staff competency.
- Checks to ensure the impartiality of official controls conducted and freedom from conflicts of interest
- In general, detailed laboratory procedures were in place and documentation supporting method validation
- The laboratories maintenance of their accreditation to ISO 17025

Each Official Food Microbiology Laboratory has been designated as an official control laboratory<sup>1</sup> for the performance of official controls in accordance with Regulation (EC) No 882/2004 and Ireland's [National Control Plan 2012-2016](#). National Reference Laboratories have also been designated for particular functions including an

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<sup>1</sup> [http://www.fsai.ie/enforcement\\_audit/laboratories/labs.html](http://www.fsai.ie/enforcement_audit/laboratories/labs.html)

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oversight role of official control laboratories and also specific duties regarding the testing of isolates in foods and for the reporting of these results.

From an organisational viewpoint, the Food Safety Laboratory Service does not have a central management structure and single contact point within the HSE for the co-ordination and management of the Official Food Microbiology Laboratory group nationally, which currently does not fully meet the requirements of Section 4.2 of the HSE Service Contract with the FSAI.

The audit team observed that in general, a comprehensive audit system was in place in each of the laboratories as part of their fulfilment of ISO 17025 requirements for accreditation purposes (subject to certain exceptions highlighted below).

However the internal audit function as part of the HSE's compliance with Article 4.6 of Regulation (EC) No 882/2004 is not in place and does not fully comply with Schedule 2, Section 1.20 of the FSAI Service Contract.

The audit team was informed that a lack of resources, e.g. laboratory personnel, equipment, etc., and receipt of funding and backing for certain projects has at times, directly impacted on method development and expansion of the scope of accreditation within the three laboratories audited.

Variations in approach to the performance of official controls were observed by the audit team when comparing the laboratories audited, which collectively could not be considered as fully consistent:

- In relation to the reporting of results of microbiological analysis, i.e. for Regulation (EC) No 2073/2005 quantitative testing, both the Limerick and Galway University Hospital Official Food Microbiology Laboratory/Public Health Laboratory do not apply the uncertainty of measurement calculated to the reported results, whilst Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory apply the uncertainty of measurement and subtract it from the final result reported
- The audit team observed differences regarding the selection of and participation in proficiency test schemes between Official Food Microbiology Laboratories audited, although they are testing for common microbiological parameters and food matrices, i.e. separate to differences in individual Official Food Microbiology Laboratory specialisations
- The Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory specifies timeframes for analysis of food samples and the reporting of results for both food and water samples. Both the Limerick and Galway University Hospital Public Health Laboratory/Official Food Microbiology Laboratories do not specify these requirements in their laboratory procedures
- The audit team observed some variations regarding the selective and recovery media to be used for certain cultural methods, as recommended by the ISO standard's specification. However, these had been fully validated and had been demonstrated as fit for purpose in each of the laboratory's audited

The audit team confirmed that samples were in general, not rejected by each of the laboratories for temperature deviations. In most cases, these occurrences were flagged on the reports issued by the Official Food Microbiology Laboratories. The audit team observed certain instances however, where the temperature of samples, i.e. at intake to laboratory, was missing on some reports issued by the Galway University Hospital Public Health Laboratory/Official Food Microbiology Laboratory.

A number of specific findings were observed at the Limerick Public Health Laboratory/Official Food Microbiology Laboratory on the day of the audit:

- A validation report was not available for the laboratory's procedure for *Listeria monocytogenes* and other *Listeria* species testing

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- A documented review in order to confirm that validations continued to be appropriate and fit for purpose, for certain methods, had not taken place recently, i.e. in some cases not since at least 2006
- A documented review that the uncertainty of measurement established for methods remains suitable/appropriate, was not being routinely recorded by the laboratory

The audit team observed in a number of cases in each of the three Official Food Microbiology Laboratories that bacterial isolates were not always being sent to the relevant National Reference Laboratory for food isolates, but were frequently being sent to one of the HSE clinical reference laboratories. The National Reference Laboratories for food have been designated for these functions in accordance with Ireland's National Control Plan 2012 – 2016, i.e. as part of Regulation (EC) No 882/2004 requirements, and consequently, this does not fully comply with requirements for the testing of food isolates.

An internal audit system was in place within the Official Food Microbiology Laboratories in order to comply with the requirements of ISO 17025. In general, detailed audits were being conducted with effective closeout of non-conformities identified.

A number of observations were made however, as part of the FSAI audit:

- In the case of the Sir Patrick Dun's Public Analyst Laboratory (Official Food Microbiology Laboratory), the laboratory's internal audit schedule had fallen behind for 2014, i.e. for vertical audits and consequently, not all scheduled Internal audits had been conducted at the time of the FSAI audit

In some cases however, for less frequently used methods and/or non-accredited methods, these were not always subject to the same degree of audit verification within the Official Food Microbiology Laboratories visited. For example:

- In the case of the Sir Patrick Dun's Public Analyst Laboratory (Official Food Microbiology Laboratory), the *Campylobacter* PALM SOP 4003 was audited less frequently than other routine methods used
- For the Limerick Public Health Laboratory/Official Food Microbiology Laboratory, the audit team observed that for *E. coli* O26 testing, i.e. which is currently a non-accredited test, this was not subject to internal or external audits in 2013 and 2014
- For Galway University Hospital Public Health Laboratory/Official Food Microbiology Laboratory, the audit team observed that for yeast and mould testing, i.e. which is currently a non-accredited test, this was not subject to regular internal or external audits

The audit team confirmed that in general, progress has been made in closing out recommendations from the FSAI's Scientific Subcommittee Report<sup>2</sup>. However, completion of their close-out will need to continue to be coordinated through the FSAI's meetings with both the Environmental Health Service and Food Safety Laboratory Service.

A number of recommendations have also been highlighted in Section 5.2 of this report which should be considered by the Food Safety Laboratory Service/FSAI (and Environmental Health Service, where applicable) for their implementation in order to address additional opportunities for improvement suggested to the current system of official controls in place.

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<sup>2</sup> <https://www.fsai.ie/WorkArea/DownloadAsset.aspx?id=11989>

### **3. INTRODUCTION**

#### **3.1 Audit Objective**

The primary objective of the audit was to assess compliance of HSE Official Food Microbiology Laboratories with Regulation (EC) No 882/2004 and service contract obligations. This included verification of the effectiveness, appropriateness and suitability of official controls performed.

#### **3.2 Audit Scope**

During the audit, the FSAI confirmed whether the HSE Official Food Microbiology Laboratory's official control activities complied with the audit criteria specified in Section 3.3 below of this report, in relation to the testing/analysis and reporting performed, i.e. in accordance with the FSAI Service Contract and in particular, Regulation (EC) No 882/2004 and associated legislation.

#### **3.3 Audit Criteria and Reference Documents**

- FSAI Service Contract including relevant legislation specified in Schedule 1 [Service Contract HSE \(Official Food Microbiology Laboratories\)](#)
- [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 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- [Regulation \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended
- [Regulation \(EC\) No 853/2004](#) laying down specific hygiene rules for food of animal origin, as amended
- [Regulation \(EC\) No 854/2004](#) laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, as amended
- [Regulation \(EC\) No 2073/2005](#) on microbiological criteria for foodstuffs, as amended
- National Control Plan for Ireland 2012-2016 (MANCP)
- [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
- Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, as amended
- Food and Veterinary Office Report: "*Overview of Findings in relation to laboratories arising from audits conducted by the FVO*".

Reference Documents:

- [Guidance for Irish National Reference Laboratories and Official Laboratories on the Implementation of Regulation \(EC\) No 882/2004 for Feed and Food Law, Animal Health and Welfare Rules](#)
- [EC Guidance document on official controls, under Regulation \(EC\) No 882/2004 concerning microbiological sampling and testing of foodstuffs](#)
- Relevant aspects of ISO 17025 that also relate to the FSAI Service Contract and Regulation (EC) No 882/2004
- FSAI Guidance Note No. 3: i.e. Original Guidance Note No.3 (2001) and the interim Guidance Note No.3 (2007)
- FSAI [Guidance Note No. 3 \(2014\)](#) (Revision 1)
- FSAI [Guidance Note No. 27](#) (2014) on the Enforcement of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs

### **3.4 Audit Methodology**

The Audit of Compliance of HSE Official Food Microbiology Laboratories with Regulation (EC) No 882/2004 and service contract obligations was carried out as part of the planned programme of audits undertaken by the FSAI.

A briefing note, i.e. explaining the audit project, and a pre-audit questionnaire were circulated in advance of on-site audit activities. Three of the seven HSE Official Food Microbiology Laboratories were randomly selected to be visited as part of the on-site verification process as no significant differences were observed between laboratories, i.e. when comparing the results of the pre-audit questionnaire received.

An evaluation plan was circulated to each of the three laboratories selected in order to provide details of the on-site audit activities to be conducted by the audit team.

During the audit, the FSAI confirmed whether the HSE Official Food Microbiology Laboratory's official control activities complied with the audit criteria specified in Section 3.3 of this report, in relation to the testing/analysis and reporting performed, i.e. in accordance with the FSAI Service Contract and in particular, Regulation (EC) No 882/2004 and associated legislation.

In preparation for this audit, the FSAI also met with the Irish National Accreditation Board (INAB) in order to confirm the scope of ISO 17025 accreditation audits performed by them. During the audit, the FSAI team did not presume that all aspects of legislation and FSAI Service Contract requirements were automatically covered by the laboratory's accreditation to ISO 17025. The audit team required evidence that these aspects were being fulfilled which was demonstrated by the Official Food Microbiology Laboratories audited.

The on-site audit component was completed during one full working day in each Official Food Microbiology Laboratory. The audit team met with the relevant laboratory and management personnel during the audit process. In order to demonstrate fulfilment of requirements, access was also provided to laboratory's information management system (LIMS), procedures, and records. These included internal and external audit reports, details regarding the Official Food Microbiology Laboratory's participation in proficiency testing and the associated results, validation reports for methods used, and the interaction with National Reference Laboratories, i.e. as part of their oversight and statutory role, as evidence supporting compliance.

A closing meeting was held following the completion of the on-site audit activities with each Official Food Microbiology Laboratory. A report of preliminary audit findings was sent to each of the laboratories audited.

## **4. AUDIT FINDINGS**

Reports of the Audit of Compliance of Official Food Microbiology Laboratories with Regulation (EC) No 882/2004 and service contract obligations are captured in the following sections of this report:

4.1 *HSE - Public Analyst's Laboratory (Official Food Microbiology Laboratory), Sir Patrick Dun's Hospital, Dublin*

4.2 *HSE - Public Health Laboratory (Official Food Microbiology Laboratory), Raheen, Limerick*

4.3 *HSE - Public Health Laboratory (Official Food Microbiology Laboratory), Galway University Hospital*

Audit conclusions and recommendations following completion of the individual audits are highlighted in Sections 5 of this report. Audit findings requiring corrective action are highlighted in the corrective action plan hyperlinked in Section 6.

### **4.1 Audit Findings: Health Service Executive, Public Analyst's Laboratory (Official Food Microbiology Laboratory), Sir Patrick Dun's Hospital, Dublin**

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##### **4.1.1 Organisation and Structure of Official Controls**

###### **(a) Designation of Official Control Laboratories**

***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.***

***Article 12 of Regulation (EC) No 882/2004 requires competent authorities to designate accredited laboratories to carry out analyses of samples taken in the context of official controls:***

Sir Patrick Dun's, Public Analyst Laboratory for microbiology has been designated as an accredited laboratory, i.e. to ISO 17025:2005, for the performance of official controls in accordance with the requirements of Regulation (EC) No 882/2004. The Public Analyst Laboratory operates as an Official Food Microbiology Laboratory for food control testing as part of the Food Safety Laboratory Service and is included in the FSAI Service Contract with the HSE.

The main part of the laboratory's activities involves the analyses of samples that have been taken by environmental health officers (EHOs) as part of their supervisory function and in the course of their visits to food business operators. These samples are taken to support inspection, as part of monitoring and surveillance programmes or as part of the investigation of an outbreak, incident, food alert or consumer complaint.

In addition to the analyses of official control samples the laboratory also performs some private testing for clients.

**(b) Organisational Structure of the Food Safety Laboratory Service (Official Food Microbiology Laboratories) within the HSE**

***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.***

***Section 4.3 of the FSAI Service Contract: The Food Safety Laboratory Service shall function as 'official laboratories' as defined in Regulation (EC) No 882/2004 and as per procedures agreed with the Authority.***

As part of the Food Safety Laboratory Service, the HSE has nine official laboratories involved in microbiological and chemical analysis of food. These include three Public Analyst Laboratories and seven Official Food Microbiology Laboratories. One laboratory performs both functions, i.e. the Official Food Microbiology Laboratory at Sir Patrick Dun's also operates as part of the Public Analyst Laboratory, where all activities are fully integrated as part of the laboratory's accreditation and quality management system. The other six Official Food Microbiology Laboratories have a slightly different set-up, working independently as public health laboratories within the HSE. Some are attached to hospitals and also perform clinical testing.

The Food Safety Laboratory Service does not however, have a central management structure within the HSE for coordination and management of the group nationally, which does not meet the requirements of Section 4.2 of the HSE Service Contract with the FSAI (HSE Service Contract Revision 2 – 14/01/2013).

*"Both parties to the service contract recognise the importance of establishing an integrated management system for the Food Safety Laboratory Service within the framework of the official agency that will provide for the overall management and coordination of the Food Safety Laboratory Service. Both parties to the contract agree that this should be established as a matter of priority".*

The audit team is aware that this issue has been highlighted over a number of years by the FSAI to the HSE management at national level without resolution to-date.

**(c) Operational Criteria Requirements**

***Article 4 of Regulation (EC) No 882/2004 requires Member States to lay down operational criteria for the competent authorities performing official controls.***

***Article 4(2) The competent authorities shall ensure:***

- ***Staff performing controls are free of any conflict of interest***
- ***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***

***Article 4(4) Competent authorities shall ensure impartiality, consistency and quality of official controls at all levels***

***Article 4(6) Competent authorities shall carry out internal audits or may have external audits carried out***

***In accordance with Schedule 2, 1.1 of the service contract, the official agency will provide staff and all resources required to ensure delivery of service outputs/activity required.***

According to Sir Patrick Dun's (Official Food Microbiology Laboratory/Public Analyst Laboratory) the laboratory has adequate staff to provide for the FSAI Service Contract requirements.

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During 2013 and 2014 however, there was considerable disruption in the availability of permanent staff due to illness and on-going maternity leave. Sir Patrick Dun's has responded by redeploying staff from the water laboratory to do food control work where possible, and by taking on agency staff where essential to the maintenance of service. It has been possible in this way to maintain the food control service. The laboratory however, is down one whole time equivalent (WTE) microbiology position for food control.

The audit team was informed that the lack of resources has adversely affected the laboratory by impacting on development of the service and extension of scope of accreditation.

**Table 1: Overview of Resources in Sir Patrick Dun's Official Food Microbiology Laboratory/Public Analyst Laboratory**

Grade/Title (31 <sup>st</sup> Dec 2013)	Staff - All Duties		Staff Engaged in any Food Control Activity		
	Total number of posts ( <sup>1</sup> WTE)	Total number of posts filled ( <sup>1</sup> WTE)	Total (number of staff)	Total number of posts filled ( <sup>1</sup> WTE)	<sup>2</sup> Total number of posts ( <sup>1</sup> WTE)
Public Analyst	1	1	1	0.2	0.2
Deputy Public Analyst	1	1	1	0.8	0.8
Executive Analytical chemist (Microbiology)	3	3	4 (1 acting*)	2	2
Senior Technician	2	2	2 #	2	2
Technician	6	6	5 † §	5	5
Clerical Officer	1	1	1	0.5	0.5
<b>Total</b>	<b>13</b>	<b>13</b>	<b>2</b>	<b>10.3</b>	<b>10.3</b>

<sup>1</sup> WTE- Whole Time Equivalent. <sup>2</sup> No. of posts identified in 1<sup>st</sup> Service Contract + no. of additional approved posts (filled + unfilled)

**Comments on Table 1:**

† Reduced to five when a technician was appointed acting senior technician. No back-fill following regularisation of senior post.

# 1 acting (to replace technician promoted to Executive Analytical chemist (Microbiology)) Made permanent following regularisation of long-term acting post without back-fill.

\* Acting position covers maternity leave of ten months.

§ 1 unavailable for seven months due to maternity leave. No cover.

Staff training and competency is extensively covered as part of the Sir Patrick Dun's Public Analyst's quality management system and procedures operated by the laboratory and as part of their accreditation to ISO

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17025:2005(E). The audit team was informed that “All staff are fully trained for the tasks to be carried out” (see also Section 8 of this report).

In accordance with Article 4.2 of Regulation (EC) No 882/2004 and Schedule 3 of the FSAI Service Contract, competent authorities are required to ensure that appropriate and properly maintained facilities and equipment are available for staff performing official controls.

Sir Patrick Dun’s Public Analyst Laboratory informed the audit team that:

*“The building is adequate but not ideal. Facilities are adequate for current requirements. The laboratory has no potential for further expansion within the current building. Equipment is adequate for current needs but much of the equipment is nearing the end of its useful life. The laboratory needs to commence a programme of progressive replacement. IT systems are in need of upgrade. The HSE is commencing a programme of PC upgrade to Windows 7 from the current Windows 5”.*

In accordance with Regulation (EC) No 882/2004, competent authorities must ensure the impartiality, quality and consistency of official controls and that staff free from conflict of interest. Recital (14) of Regulation (EC) No 882/2004 requires that official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality. Procedures are in place in the Sir Patrick Dun’s Public Analyst Laboratory which cover these requirements and are reviewed for their effectiveness (see Sections 4 and 10 of this report for further details).

In addition to official controls, the laboratory also carries out a certain amount of private testing for clients (FSAI pre-audit questionnaire):

*“It is a small portion of the work carried out. We offer a service to members of the public on a fee paying basis and to solicitors acting for their clients. We offer a service to companies investigating consumer complaints where we are not involved from a food control aspect. We do not take on contract work”.*

The laboratory provides testing as part of the provision of health certificates, e.g. for export, i.e. in accordance with Section 1.25 of the service contract, e.g. for products such as chocolates and cream liqueurs.

The approach taken by Sir Patrick Dun’s Public Analyst Laboratory/Official Food Microbiology Laboratory to ensure that staff carrying out official controls are free from any conflict of interest in accordance with Regulation (EC) No 882/2004 Art. 4.2 (b) requirements is as follows (FSAI pre-audit questionnaire):

- “All staff have acknowledged reading of the HSE code of standards”
  - “It is part of contract of employment”
  - “Quality manual 4.1 (d) addresses the issue”
- “Avoidance of conflict of interest is part of the traditional ethos of Public Analyst Laboratories”.

## **4.1.2 Coordination and Planning of Official Controls**

### **(a) Sampling and Analysis**

***Arrangements are specified for the coordination of sampling and analysis between Environmental Health Service and Food Safety Laboratory Service In accordance with section 3.2 of the FSAI service contract. Issues relating to coordination of sampling and analysis will primarily be dealt with through the EHO-Official Food Microbiology Laboratory-Public Analyst Laboratory sampling groups in conjunction with the Authority.***

***In accordance with clause 4.4 of the FSAI Service Contract – (official food control services to be provided) - the Food Safety Laboratory Service shall provide services for microbiological, chemical and other testing of foodstuffs for parameters including contaminants. Analysis shall be carried out in accordance with the Section 3 taking into account the relevant legislative requirements, guidelines and/or protocols.***

As part of the annual sampling programme agreed between the HSE, the Food Safety Laboratory Service and the FSAI at national level, 6,902 microbiological samples were required to be taken by the Environmental Health Service in 2014 and submitted to the relevant Food Safety Laboratory Service for testing, i.e. within one of the four HSE areas. These also form part of the HSE Work Programme outputs to be met by the Environmental Health Service/Food Safety Laboratory Service in accordance with the delivery of the FSAI Service Contract requirements.

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of microbiological testing from central to regional level and local levels, as part of the national sampling programme. The audit team was provided with minutes of regional meetings between the Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory, the Cherry Orchard Public Health Laboratory/Official Food Microbiology Laboratory and the Environmental Health Service sampling representatives/coordinators.

The timing and delivery of samples is agreed locally between Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory and each of the Environmental Health Service Principal Environmental Health offices and these schedules were also provided.

The laboratory tested the sample numbers requested for analysis by the Environmental Health Service in both 2013 and 2014 and consequently, met the requirements of the FSAI work plan for service delivery.

**Table 2: Microbiological Testing of Samples Sir Patrick Dun’s Public Analyst Laboratory/Official Food Microbiology Laboratory (2013)**

<b>Sampling Activity/Reason</b>	<b>Number of Samples</b>
Routine	1,007
Repeat/Follow-up	80
Survey	169
Complaint	184
Import	57
Export	71
Control	1
Food Alert (RASFF)	0
Food Poisoning/Outbreak	0
Other - specify	-
<b>Total</b>	<b>1,569</b>

For certain specialist microbiological parameters, individual Official Food Microbiology Laboratories have also developed expertise in certain areas and provide analytical typing services on a national basis, e.g.in the case of the Sir Patrick Dun’s Public Analyst Laboratory/Official Food Microbiology Laboratory, specialisations in the food area include analytical services for:

- Vibrio parahaemolyticus
- Yeasts and moulds

Monitoring of the annual programmes for microbiological sampling was confirmed by the audit team from the minutes of the Regional Food Sampling Committee meeting (4<sup>th</sup> of June 2014) at Sir Patrick Dun’s where updates on sampling and testing were provided. In attendance were representatives from the national and regional Environmental Health Service sampling group and also representatives from the Sir Patrick Dun’s Public Analyst Laboratory and from Cherry Orchard Public Health Laboratory.

The audit team was informed that in general, there were no deviations in testing performed for both 2013 and 2014.

Occasionally, testing was rescheduled at the request of Environmental Health Service which was accommodated with no significant deviations from the agreed sampling plan in either year.

**(b) Coordination and Planning: National Meetings and Participation on Working Groups/Committees and Information Dissemination /communication**

Sir Patrick Dun’s Public Analyst Laboratory is represented on FSAI Working Groups/Committees and attends cross agency meetings relevant to the performance of official controls and in accordance with FSAI service contract requirements.

The audit team also confirmed internal meetings, i.e. including laboratory section meetings, Public Analyst Laboratory meetings for all staff and senior management and quality management review meetings take place, where topics and information relevant to coordination, planning and review of the performance of official controls are discussed.

### **4.1.3 Sample Receipt, Handling and Analysis**

#### **(a) Sample Receipt, Handling and Analysis**

***In accordance with Article 11.7 of Regulation (EC) No 882/2004 on methods of sampling and analysis, samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.***

Sir Patrick Dun's procedure: *SOP PALA 002 (issue date 31.1.14) - Reception and Handling of Test Items at the Laboratory Reception Area* – deals with the receipt and handling of samples on arrival at the laboratory.

*SOP PALA 003 (issue date 24.9.14) – Reception and Handling of Test Items at the Test Laboratories* – deals with the receipt of samples for analysis, i.e. post reception and in the laboratory section itself where analysis is conducted.

The audit team confirmed that there is an effective system in place for identifying and tracking samples from receipt to testing, for samples analysed by the laboratory. Samples are labelled, i.e. which includes a barcode, and these are also attached to the EHO submission form, i.e. which accompanies the sample during transport, where a corresponding label is attached by the laboratory. The samples are also given a unique LIMS number on the IT system which also links with the labels on the sample and the Sample Request Form, thus ensuring full analysis traceability, i.e. for samples analysed by the Sir Patrick Dun's.

Samples are either directly handed in to the laboratory by an EHO or arrive by courier/taxi that has been organised for their transport.

Where the sample is dropped in by the EHO, Sir Patrick Dun's requires them to record the temperature of the sample on the Food Safety Laboratory Service Sample Request Form on receipt at the laboratory. Where samples are dropped in by courier/taxi, Sir Patrick Dun's staff record the temperature of the sample on the Sample Request Form. A number of examples of this were crosschecked by the audit team demonstrating that the SOP was being followed in practice.

Under section 3.2 of *SOP PALA 002 'samples may not be appropriate for acceptance'*. The audit team was informed however that no samples warranted rejection for analysis in 2013/14.

In accordance with Appendix B section 5 of *SOP PALA 002, "if the temperature of the sample is < 1 or > 8oC"*, laboratory staff are required to *"try to establish a reason and record a comment on the Sample Request Form"*.

The audit team confirmed that samples are not in general, rejected for temperature deviations.

The audit team was informed that the condition of the sample on receipt is also entered on the final report issued by the laboratory, where it could impact or affect the validity of the analytical result. Reference: *SOP PALA 0026 (issue date 12.09.14) – Reporting of Results section 4.3.6.*

The audit team confirmed that the condition and temperature of samples received are also entered on the laboratory's LIMS system.

**(b) Timeframes for Analysis and Reporting of Results**

SOP PALA 0018 (issue date: 31/1/14) Test Item Delivery and Reporting according to Timeframes and Deadlines Policy. The laboratory has specified timeframes for analysing samples and reporting of results for all microbiological testing performed by the laboratory.

The audit team was informed that samples testing positive are prioritised for reporting where a direct call is made by the laboratory to the EHO who performed sampling. The audit team confirmed that samples that undergo further confirmatory testing can take time to complete analysis.

Most samples reviewed by the audit team were generally well within the laboratory's turnaround deadlines specified in *SOP ALA 0018 (issue date 31.1.14) – Test Item Delivery and Reporting according to Timeframes and Deadlines Policy*.

A number of positive samples were reviewed for turnaround time from sample being taken, to laboratory receipt, analysis performed and reporting of result to client.

The audit team confirmed that on occasion however, the four-week turnaround deadline referenced in SOP ALA 0018 (issue date 31.1.14) for reporting of microbiological results by the laboratory to the client, can be exceeded. This is primarily due to the fact that the subcontracted confirmatory analysis can extend the total analysis turnaround beyond the timeframe specified in the laboratory's procedures.

**Table 3: Turnaround Times for Sample Analysis and Reporting Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory**

Sample No.	Sample Type	Sample Date	Receipt Sir Patrick Dun's	Analysis Date	First Report	Final Report
A	Routine	29.4.14	30.4.14	30.4.14	15.5.14	N/A
B	Routine	13.5.14	13.5.14	14.5.14	30.5.14 <sup>1</sup>	24.6.14 <sup>2</sup>
C <sup>3</sup>	Complaint	-	31.1.14	4.2.14	10.2.14	N/A

Note: Sample B – <sup>1</sup>first report date 30.5.14. <sup>2</sup>second report date 24.6.14 – due to serological confirmation performed by the national reference laboratory  
 Sample C - <sup>3</sup>Temperature not recorded on report

#### **4.1.4 Documented Procedures**

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

**Recital (14) of Regulation (EC) No 882/2004 requires that official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality**

**Recital 17 of Regulation (EC) No 882/2004, laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated.**

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

The audit team looked at laboratory procedures and records relating to:

- Intake, handling and testing of samples
- Reporting of results including the collection and reporting of data to the FSAI
- Selection and validation of methods including the laboratory's scope of accreditation
- Assessment and on-going monitoring of method performance including internal quality control and participation in external proficiency testing schemes,
- Internal and external audits,
- Procedures for the control of non-conforming work
- Training of staff

At the time of the audit, a document list of procedures, i.e. "Public Analyst Laboratory (Official Food Microbiology Laboratory) Dublin – lab SOP lists" were provided. The audit team was informed that many microbiology SOPs were currently under review and that the master lists of SOPs are updated yearly.

Sir Patrick Dun's Public Analyst Laboratory procedures are reviewed every two years for test methods and every three years for supplementary methods.

The laboratory had procedures in place to verify the effectiveness of the official controls performed (see Section 10 of this report). Consequently, the audit team's view is that procedures in place were sufficiently detailed and comprehensive in order to provide adequate instructions to staff to be followed for the performance of official controls and were being kept up-to-date, which meets the requirements of Regulation (EC) No 882/2004 and the FSAI Service Contract requirements.

#### **4.1.5 Scope of Accreditation for the Performance of Official Controls**

**Competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with EN ISO/IEC 17025, i.e. 'General requirements for the competence of testing and calibration laboratories'.**

**Service Contract Reference: Accreditation (4.3.1): The Food Safety Laboratory Service of the Official Agency shall be accredited by the Irish National Accreditation Board for appropriate functions and comply with ISO/IEC 17025:2005.**

**Such accreditation must be maintained and expanded in line with requirements and available resources and the requirements of Article 11 (2) and (3) of Regulation (EC) No 882/2004.**

**The official agency will provide the Authority with up-to-date information on the scope of their accreditation.**

The scope of accreditation for Sir Patrick Dun's Laboratory (Official Food Microbiology Laboratory) as listed on the INAB website:

<http://www.inab.ie/FileUpload/Testing/-Public-Analyst-s-Laboratory-Dublin-099T.pdf>

Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory provides updates to the FSAI regarding the maintenance and scope of the laboratory's accreditation to ISO 17025, in accordance with FSAI Service Contract requirements. The schedule of accreditation was not expanded during 2013. Following the INAB visit in March 2014, the scope for *Bacillus cereus* enumeration was extended to include cereals and bakery products (INAB P9 classification .07).

The audit team confirmed that Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory maintains and expands its accreditation in line with the requirements of Article 11(2) and (3) of Regulation (EC) No 882/2004 and that the laboratory is accredited for the appropriate functions and range of tests and matrices in accordance with Regulation (EC) No 882/2004 and the requirements of the FSAI Service Contract.

The laboratory has intentions of extending their current scope of accreditation and work had commenced with the aim of achieving accreditation for enumeration of aerobic mesophilic bacteria using the TEMPO® AC system (to be presented at the next INAB visit in March 2015). The audit team was also informed that work is in progress for Polymerase Chain Reaction-based method for *Legionella* in water where it is hoped to extend the use of Polymerase Chain Reaction to the food area in the future.

At the time of the FSAI audit, the audit team observed that yeasts and moulds in food have yet to be submitted for accreditation and that relatively low numbers are tested by the laboratory.

#### **4.1.6 Performance of Official Controls -Testing/Analysis**

##### **(a) Method Selection**

**Article 11 of Regulation (EC) No 882/2004 requires that sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or, (a) if no such rules exist, with internationally recognised rules or protocols, for those agreed in national legislation; or, (b) in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.**

**In accordance with Section 4.4.4, i.e. Laboratory methods, of the FSAI Service Contract with the HSE - laboratories shall use methods that comply with Article 11 of Regulation (EC) No 882/2004. Laboratories performing the same analysis should use consistent methods to ensure comparability of results nationally.**

The approach taken by Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory for the selection of methods is as follows:

- The laboratory uses only EU reference methods or approved alternative methods, all of which have been internationally validated either through EU organised collaborative trials for reference methods or by Association Française de Normalisation for the approved alternative methods

The approach taken by Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory for the selection of methods is as follows:

- Where the method is specified in a Regulation such as 2073, they apply the specified method
- Where the method is not specified in a Regulation such as when assessment is against a guideline, an approved alternative method may be used for reasons of efficiency, e.g. Vidas *Salmonella*, TEMPO, TVC, TEMPO *E. coli*

The audit team's view is that the approach taken by Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory for selection of methods for the performance of official controls complies with Regulations (EC) No 882/2004, 2073/2005, FSAI Guidance Note No. 3 and water testing requirements reviewed.

##### **(b) Method Validation**

**Article 11.3 of Regulation (EC) No 882/2004 requires that Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III (Characterisation of Methods of Analysis): *Methods of analysis should be characterised by the following criteria: (a) accuracy;(b) applicability (matrix and concentration range); (c) limit of detection;(d) limit of determination; (e) precision;(f) repeatability; (g) reproducibility; (h) recovery;(i) selectivity; (j) sensitivity; (k) linearity; (l) measurement uncertainty; (m) other criteria that may be selected as required.***

**In accordance with Recital 17 of Regulation (EC) No 882/2004, laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated.**

The audit team confirmed that methods had been validated as part of the laboratory's accreditation to ISO 17025:2005, which also fulfilled the requirements of Regulations (EC) No 882/2004, 2073/2005 and FSAI Guidance Note No.3 requirements, i.e.:

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Original Guidance Note No.3 (2001) and the interim Guidance Note No.3 (2007), FSAI Guidance Note No. 3 Guidelines for the Interpretation of Results of Microbiological Testing of Ready-to-Eat Foods Placed on the Market (Revision 1).

Appropriate criteria had been applied in accordance with Annex III requirements of Regulation (EC) No 882/2004.

The methods for microbiological tests on food reviewed by the audit team, included:

- Detection of *Listeria monocytogenes*: SOP PALM 0017 based on ISO 11290-1:1996/Amd.1:2004
- Enumeration of *Listeria* spp and *L. monocytogenes*: SOP PALM 0018(S) based on ISO 11299-2:1999/Amd.1:2004
- Detection of *Salmonella* spp.: SOP PALM 0004 based on ISO6579:2002 Amd. 1 2007
- Elfa Detection of *Salmonella* spp using VIDAS SLM Kit.: Documented in-house method:
- SOP PALM 4001 based on Association Française de Normalisation VIDAS *Salmonella* (Vidas SLM) method BIO 12/1-04/94 (renewed 2010) Screening method. Cultural and confirmation aspects based on ISO 6579:2002 Amd. 1 2007
- Detection of *Campylobacter* spp: SOP PALM 0023 based on ISO 10272-1:2006
- Elfa Detection of *Campylobacter* spp using VIDAS CAM kit.: SOP PALM 4003 based on Association Française de Normalisation VIDAS *Campylobacter* method (VVIDAS CAM) BIO 12/29-05/10 Screening method. Cultural and confirmation aspects based on ISO 10272-1:2006
- Enumeration of *Escherichia coli* in food products using TEMPO EC(E coli) test: Documented in house method: SOP PALM 0005, Association Française de Normalisation TEMPO EC Validation BIO 12/13-02/05 (Renewed 2009)
- Enumeration of  $\beta$ -glucuronidase- positive *E.coli* by colony count at 44°C using TBX: SOP PALM 0026 based on ISO 16649-2:2001

According to the FSAI audit pre-audit questionnaire, the approach taken by Sir Patrick Dun's Official Food Microbiology Laboratory is outlined as follows:

*"The laboratory demonstrates that it can successfully apply the methods through a verification process based on satisfactory participation in external quality assurance schemes for all the methods, determination of Measurement Uncertainty for the methods as applied in the laboratory (based on ANOVA) and demonstration the laboratory can achieve a suitable detection limit".*

The laboratory stated that it had also participated in the collaborative trials which established many of the reference methods.

The audit team found that for all test methods reviewed the uncertainty of measurement, limit of detection and limit of quantification were determined, where relevant. Each method had been deemed appropriate and approved by the Technical Manager. The uncertainty of measurement, limit of detection and limit of quantification were acceptable in all methods reviewed. Methods were reviewed for fitness for purpose every two years and validation reports were updated as required. All methods selected for use were either ISO standard procedures or alternative proprietary methods validated according to ISO 16140.

### (c) Participation in External Quality Assurance - Proficiency Test Schemes

The laboratory actively participates in selected external quality assurance and results were satisfactory. Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory does not participate in the European Food Microbiology Legislation Scheme.

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In relation to any instances of laboratory results differing from those expected, a detailed root cause analysis was carried out in each case, i.e. as part of the laboratory's non-conforming work procedures. The audit team confirmed that appropriate investigation(s) took place and no impact on test results was identified.

The laboratory participates in the Public Health England Food Microbiology standard scheme. It does not participate in the European Food Microbiology Legislation Scheme, which the other two laboratories do.

### (d) Subcontracting of Methods of Analysis

According to Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory the approach taken for subcontracting of methods of analysis is as follows (FSAI pre-audit questionnaire):

- "We send *Listeria monocytogenes* and *Salmonella* bacterial strains to National Reference Laboratory (Backweston and Galway, respectively) for serological characterisation and *S. aureus* from dairy samples to Backweston National Reference Laboratory for toxin testing all at the request of the FSAI"
- "Other than the above, we do not take on work that would involve sub-contraction. Should sub-contraction become necessary, the laboratory Quality Manual (4.5) specifies procedures to be followed"
- "Criteria used for the subcontracted work, is for the laboratories to be used that have been specified by the FSAI. We cooperate with National Reference Laboratories. We do not have service level agreements for such work"

The audit team observed however, that in a number of instances, *Listeria* isolates were not sent to the Department of Agriculture, Food and the Marine's (DAFM) National Reference Laboratory in Backweston, which was not fully in accordance with the approach indicated by the laboratory as part of the pre-audit questionnaire submitted to the FSAI. Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory agreed to forward these to the National Reference Laboratory. The audit team confirmed that *Salmonella* isolates were being submitted to the National salmonella Reference Laboratory.

### 4.1.7 Performance of Official Controls: Reporting of Results and Data

#### (a) Reporting, Designation and Certification

***In accordance with Section 4.4.5, i.e. reporting, designation and certification, of the FSAI Service Contract with the HSE - the Food Safety Laboratory Service shall agree and implement a consistent approach to the reporting of results of analysis at national level, including designation, observations, and certification; taking into account the requirements of Environmental Health Service and the Authority.***

***In accordance with Section 1.8, i.e. information systems, of the FSAI Service Contract with the HSE - the Official Agency Food Safety Laboratory Service shall transfer data on individual food samples taken under this contract, electronically to the Authority from the laboratory LIMS. The FSAI shall collate and analyse national data based on the data transmissions from Food Safety Laboratory Service.***

***Schedule 2, 1.7 of the FSAI Service Contract with the HSE - refer to the annual work programme requirements regarding specific targets and measureable outcomes to be met, i.e. Appendix 1: Table 1 - 30th May 2014 - for Quarter 3 and 4 2014.***

In accordance with the annual work programme requirements for 2014, the following targets and measureable outcomes have been specified:

- Proposal for a standard suite of tests (Q2 2014)
- Standard approach to designation and reporting of results to be proposed including subcontracted tests and results (by end of 2014)

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The audit team confirmed that a standard suite of tests had been agreed between the FSAI and the Official Food Microbiology Laboratories in 2014. An implementation date of 1st of January 2015 has been agreed by the Official Food Microbiology Laboratories.

The audit team confirmed that a draft document had been developed for the purposes of national designation of samples and reporting of results (issue date 21.10.14), which had yet to be fully agreed by the Official Food Microbiology Laboratory group, before being implemented .i.e.: *“Official Food Microbiological Laboratories National Policy on Interpretation of Microbiological Results and Designation of Official Control Food Samples”*.

### (b) Reporting of Data to the FSAI

In accordance with the annual work programme requirements for 2014, the following targets and measurable outcomes have been specified:

- *Data and reports specified in Schedule 4 and Section 48(8) are submitted to the Authority (data@fsai.ie) in the format and timeframe specified in the schedule (by three weeks after reporting period and by 31<sup>st</sup> March each year) and other data reports where agreed*
- *LIMS – HSE Labs LIMS extracted data to be sent each week between Friday 1700 and Monday 0700,*
- *week in arrears*
- *Labs to evaluate their LIMS compatibility with National Data Standards and EFSA’s SSD2 data standard with a view to planning updates to improve compliance*

The audit team confirmed that Sir Patrick Dun’s Public Analyst Laboratory/Official Food Microbiology Laboratory had configured their LIMS extracts for both sample and reporting designations in accordance with the data transmissions/extracts format requested by the FSAI.

The LIMS extract however, does not include subcontracted tests, e.g. the subcontracting of test isolates to the National Reference Laboratory.

### 4.1.8 Staff Performing Official Controls

**Article 6 of Regulation (EC) No 882/2004 requires that competent authorities shall ensure that all of its staff performing official controls:(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. (b) keep up-to-date in their area of competence and receive regular additional training as necessary;**

***In accordance with Section 1.17 Continuing Professional Development in Food Safety Activities, of the FSAI Service Contract with the HSE - the official agency shall ensure that appropriate training, including induction training, is provided for staff performing official controls in line with Article 6(a) and Annex II, Chapter 1 of Regulation (EC) No 882/2004. Training records must be maintained for all staff performing official controls.***

The approach taken by Sir Patrick Dun’s Public Analyst Laboratory/Official Food Microbiology Laboratory regarding competency and training of staff, CPD and maintenance of competency is as follows:

- Training procedure is described in administrative SOP PALA 0012. Staff training files are maintained
- Continued competence is addressed in SOP PALM 0205 Section 3.1.8 – use of external quality assurance schemes. Where appropriate, staff may attend seminars, workshops and other events relevant to their work
- In recent years funding for external training has been very restricted
- In 2014, the laboratory has spent time developing capacity for *Legionella* testing in water and has had approximately four days of training from the supplier on Polymerase Chain Reaction aspects. The laboratory hopes to transfer these skills to the food testing area in the future.

- The approach taken during audits, e.g. witness tests, looks at operational application of testing in accordance with procedures which confirms correct implementation of procedural requirements and verification that staff are appropriately trained.

Assessments of training and competency are covered as part of the Sir Patrick Dun's Public Analyst Laboratory's own quality management system and as part of the laboratory's accreditation to ISO 170125:2005 where it is subject to routine assessments. The audit team's view is that training and competency of staff within laboratory is effective and meets the requirements of Regulation (EC) No 882/2004 and the FSAI Service Contract. Evidence of the performance of staff training and competence was seen via the results of external quality assurance, internal quality assurance and test witness audits, which were provided to the audit team.

#### **4.1.9 Interaction and Cooperation with National Reference Laboratories**

***In accordance with Section 4.3 (Official Laboratories), of the FSAI Service Contract with the HSE - The Food Safety Laboratory Service shall function as 'official laboratories' as defined in Regulation (EC) No 882/2004 and as per procedures agreed with the Authority. They shall co-operate with the National Reference Laboratories for food testing in Ireland in the discharge of their functions under Article 33 of the Regulation and as per agreed protocols with the Authority.***

Official laboratories are required to cooperate with the relevant National Reference Laboratory in the fulfilment of the National Reference Laboratory role of coordinating the activities of official laboratories in their area of competence. Official laboratories for food are obliged under the service contract to the FSAI to co-operate with the National Reference Laboratories in the latter's discharge of their functions under Article 33 of the Regulation. This may include: providing all information to the National Reference Laboratory on request, on the methods of analysis used in the official laboratory; requesting technical assistance from the National Reference Laboratory on methods of analysis within the National Reference Laboratories area of competence; providing information to the National Reference Laboratory on request on the comparative tests that the official laboratory is participating in.

To assist National Reference Laboratories in their role of monitoring and identifying emergent trends, official laboratories are required to provide information, samples/specimens, isolates to the National Reference Laboratory, on request.

The list of National Reference Laboratories and official laboratories designated for official controls under Regulation (EC) No. 882/2004 can be found at the following URL:  
[http://www.fsai.ie/enforcement\\_audit/monitoring/national\\_official\\_labs.html](http://www.fsai.ie/enforcement_audit/monitoring/national_official_labs.html)

The audit team confirmed the following interaction with the National Reference Laboratories:

- Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory has provided information to National Reference Laboratories on both methods of analysis, e.g. most recently concerning *L. monocytogenes* in October 2014, when requested
- Technical assistance from the National Reference Laboratories has not yet been required
- Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory has provided information to National Reference Laboratories on participation and performance in external quality assurance schemes when requested
- Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory has recently participated successfully in an external quality assurance round on *Listeria monocytogenes* organised by the National Reference Laboratory and facilitated direct reporting of results to the National Reference Laboratory

In relation to subcontracting of this testing, Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory stated that:

*“We send Listeria monocytogenes and Salmonella bacterial strains to National Reference Laboratory (Backweston and Galway, respectively) for serological characterisation and S. aureus from dairy samples to Backweston National Reference Laboratory for toxin testing all at the request of the FSAI”.*

The audit team observed however, at the time of the audit in 2014, that a number of *Listeria monocytogenes* samples had not been sent to the National Reference Laboratory in Backweston. The laboratory agreed to send these to the National Reference Laboratory following this audit finding.

The audit team was informed that in relation to the reporting of results for 2073/2005 analysis, Sir Patrick Dun’s Public Analyst Laboratory/Official Food Microbiology Laboratory apply an uncertainty of measurement to the result designation and the uncertainty of measurement is subtracted as part of the quantification and determination of the result reported.

#### **4.1.10 Verification and Review of the Performance of Official Controls**

**Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.**

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

**Article 4(6) of Regulation (EC) No 882/2004 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.**

The approach taken by the Sir Patrick Dun’s Public Analyst Laboratory/Official Food Microbiology Laboratory to ensure the effectiveness and appropriateness of official controls is via the following process, i.e. reference FSAI audit pre-audit questionnaire:

- *“Having a policy of maintaining a scope of accreditation and extending it wherever possible”*
- *“Participating extensively and successfully in external quality assurance schemes”*
- *“Maintaining a robust internal quality assurance programme”*
- *“Participation in regular meetings with the FSAI”*
- *“Cooperation with the National Reference Laboratory”*

##### **(a) Scope of Accreditation**

The laboratory takes a proactive approach to reviewing and extending their scope of accreditation, i.e. to include additional methods and matrices, as required and where feasible, in order to meet the requirements of Regulations (EC) No 882/2004, 2073/2005 and the FSAI Service Contract. For example:

- A number of methods were in the process of being submitted as part of the extension to scope to be assessed during the next INAB surveillance visit in 2015, i.e. for enumeration of aerobic mesophilic bacteria using the TEMPO® AC system, and
- Work is in progress for Polymerase Chain Reaction-based method for *Legionella* in water. It is hoped to extend the use of Polymerase Chain Reaction to the food area in the future testing in the near future

### **(b) Internal Quality Assurance**

INAB audits confirmed that appropriate internal quality assurance is carried out by the Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory to support test assurance.

### **(c) External Quality Assurance Schemes**

Verification of performance is assessed via the laboratory's active participation in external proficiency test schemes and their associated results. The audit team confirmed that the laboratory performed well in most proficiency test assessments and for those that did not achieve the expected result, these were adequately investigated to ensure that there was no impact on the quality of customer results relevant to the FSAI audit.

The proficiency test schemes used and laboratory's performance are also assessed by DAFM (National Reference Laboratories in Backweston) on an annual basis. Reports for 2012 and 2013 deemed the laboratory's performance to be satisfactory in both years for the proficiency tests participated in.

### **(d) Internal and External Audits**

External audits are conducted by INAB as part of the laboratory's accreditation to ISO 17025:2005. The laboratory provided the audit team with the external audit reports for 2013 and 2014. A systematic and thorough approach was applied for closing out non-conformances highlighted during INAB surveillance assessments. Non-conformances had been cleared for both 2013 and 2014.

The audit team observed that an internal audit system, as part of the HSE's compliance with the requirements of article 4.6 of Regulation (EC) No 882/2004, is not in place. This also does not fully comply with Schedule 2 Section 1.20 of the FSAI's Service Contract and Appendix 1 (1.20) of the FSAI's Work Programme.

Internal audits are carried out as part of the laboratory's accreditation to ISO 17025:2005 covering the full remit of laboratory's accreditation. 'Vertical audits' are performed in each microbiology section in the course of the year. 'Test witness audits' are carried out in one of the microbiology sections in the Sir Patrick Dun's Public Analyst Laboratory during the course of the year, covering a range of parameters that have not been witnessed during the previous year. All regularly used methods are subject to test witnessed audits over a period of three years. Less routinely used methods however, are not reviewed as frequently, e.g. *Campylobacter* PALM SOP 4003.

At the time of the audit, a vertical audit for *Listeria* spp. was in progress. The laboratory's internal audit schedule had fallen behind for 2014, i.e. for vertical audits and consequently, not all scheduled internal audits had been conducted.

### **(e) Meetings**

Regular internal meetings take place as part of the planning, coordination and review of official controls conducted and their performance, including a yearly management review. The Sir Patrick Dun's Public Analyst Laboratory attends FSAI working groups and committees where up-to-date/relevant information is disseminated to staff within the Sir Patrick Dun's Public Analyst Laboratory.

### **(f) Review of Procedures**

The laboratory's procedures are also reviewed on a scheduled basis, i.e. every two years for test methods and every three years for supplementary methods in order to confirm and reflect their continued suitability and effectiveness. The Sir Patrick Dun's Public Analyst Laboratory's quality manual and procedures also deal with impartiality and conflict of interest.

In general, the audit team's view is that effective performance of official controls is demonstrated via the laboratory's maintenance of its accreditation as part of its quality management system, performance in external quality assurance, internal quality assurance, internal and external audits, coordination and review meetings, training of staff and review of procedures, which support and confirm the quality and consistency of official controls performed at the Sir Patrick Dun's Public Analyst Laboratory/Official Food Microbiology Laboratory.

#### **4.1.11 Report of the Scientific Committee of the Food Safety Authority of Ireland**

***In accordance with Section 3 of the FSAI Service Contract, the Recommendations of the Authority's Scientific Committee report on sampling and microbiological examinations undertaken by the official agency will be reviewed and implemented in line with the actions agreed with the Authority and the official agency.***

***"Review of the Sampling and Microbiological Examinations undertaken by the Health Service Executive, 2007 and 2008": <https://www.fsai.ie/WorkArea/DownloadAsset.aspx?id=11989>***

The audit team confirmed that progress had been made with closing out the scientific committees recommendations. Consequently, at the time of the audit, several recommendations had been fully closed, whilst others were still a work in progress. Coordination of their close-out was being managed by the FSAI through on-going communications and via regular meetings with the Environmental Health Service and Food Safety Laboratory Service.

## **4.2 Audit Findings: The Health Service Executive, Public Health Laboratory (Official Food Microbiology Laboratory), Limerick**

### **Report of the Audit of Compliance of Official Food Microbiology Laboratories with Regulation (EC) No 882/2004 and Service Contract Obligations**

#### **4.2.1 Organisation and Structure of Official Controls**

##### **(a) Designation of Official Control Laboratories**

***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.***

***Article 12 of Regulation (EC) No 882/2004 requires competent authorities to designate accredited laboratories to carry out analyses of samples taken in the context of official controls:***

Limerick Public Health Laboratory has been designated as an accredited laboratory, i.e. to ISO 17025:2005, for the performance of official controls in accordance with the requirements of Regulation (EC) No 882/2004. The Public Health Laboratory operates as an Official Food Microbiology Laboratory for food control testing as part of the Food Safety Laboratory Service and as part of the FSAI Service Contract with the HSE. The Public Health Laboratory Limerick performs water testing for University Limerick Hospital Group, food and water testing for Community Healthcare Organisation Area 3 (Limerick, Clare and East Limerick/North Tipperary) and also water testing for the National Standards Authority (NSAI) on an annual basis.

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The main part of the laboratory's activities involves the analyses of samples that have been taken by EHOs as part of their supervisory function and in the course of their visits to food business operators. These samples are taken to support inspection, as part of monitoring and surveillance programmes, or as part of the investigation of an outbreak, incident, food alert or consumer complaint.

In addition to the analyses of official control samples the laboratory also performs some private testing for clients.

### (b) Organisational Structure of the Food Safety Laboratory Service (Official Food Microbiology Laboratories) within the HSE

**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.**

**Section 4.3 of the FSAI Service Contract: The Food Safety Laboratory Service shall function as 'official laboratories' as defined in Regulation (EC) No 882/2004 and as per procedures agreed with the Authority.**

As part of the Food Safety Laboratory Service, the HSE has nine official laboratories involved in microbiological and chemical analysis of food.

These include three Public Analyst Laboratories and seven Official Food Microbiology Laboratories.

The Limerick Public Health Laboratory is not linked to any Public Analyst Laboratory and operates independently as an Official Food Microbiology Laboratory within the HSE.

The Food Safety Laboratory Service does not however, have a central management structure within the HSE for coordination and management of the group nationally, which does not meet the requirements of Section 4.2 of the HSE Service Contract with the FSAI (HSE Service Contract Revision 2 – 14/01/2013).

"Both parties to the service contract recognise the importance of establishing an integrated management system for the Food Safety Laboratory Service within the framework of the official agency that will provide for the overall management and coordination of the Food Safety Laboratory Service. Both parties to the contract agree that this should be established as a matter of priority".

The audit team is aware that this issue has been highlighted over a number of years by the FSAI to the HSE management at national level, without resolution to-date.

### (c) Operational Criteria Requirements

**Article 4 of Regulation (EC) No 882/2004 requires Member States to lay down operational criteria for the competent authorities performing official controls.**

**Article 4(2) The competent authorities shall ensure:**

- **Staff performing controls are free of any conflict of interest**
- **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**

**Article 4(4) Competent authorities shall ensure impartiality, consistency and quality of official control at all levels**

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**Article 4(6) Competent authorities shall carry out internal audits or may have external audits carried out in accordance with Schedule 2, 1.1, of the service contract the official agency will provide staff and all resources required to ensure delivery of service outputs/activity required.**

According to the Limerick (Official Food Microbiology Laboratory/Public Health Laboratory) the laboratory has adequate staff to provide for the FSAI Service Contract requirements.

The audit team was informed that there has been some ongoing disruption in the availability of permanent staff due to difficulties with filling of maternity leave. The laboratory's funding is linked to the hospital services budget and consequently, for the approval/funding for the filling of staff positions is dependent on being sanctioned by hospital management.

Two temporary staff were taken on in 2014 to cover maternity leave at the laboratory.

The audit team was informed that the lack of resources has impacted on progress with new method validation.

**Table 1: Overview of Resources in Limerick Official Food Microbiology Laboratory/Public Health Laboratory**

Grade /Title (31 <sup>st</sup> Dec 2013)	Staff - All Duties		Staff Engaged in any Food Control Activity		
	Total number of posts ( <sup>1</sup> WTE)	Total number of posts filled ( <sup>1</sup> WTE)	Total (number of staff)	Total number of posts filled ( <sup>1</sup> WTE)	<sup>2</sup> Total number of posts ( <sup>1</sup> WTE)
Consultant Microbiologist	2	2	2	0.1	0.1
Chief Medical Scientist	1	1	1	0.2	0.2
Senior Medical Scientist	2	2	2	2	2
Medical/Food Scientists	4	3.2	4	3.2	4
Laboratory Assistant	1	1	1	1	1
Administration	0	0	0	0	0
Laboratory Porter	0.1	0.1	1	0.1	0.1
<b>Total</b>	<b>10.1</b>	<b>9.3</b>	<b>11</b>	<b>6.6</b>	<b>7.4</b>

<sup>1</sup>Note: Staff - All Duties is used to record the total number of staff in the laboratory. If all of the staff in the laboratory are involved in food activities this section can be left blank and insert a note in the box below that all staff are involved in food activities.  
<sup>1</sup>WTE- Whole Time Equivalent

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Staff training and competency are extensively covered as part of the Limerick Public Health Laboratory/Official Food Microbiology Laboratory quality management system and procedures as part of their accreditation to ISO 17025:2005(E). The audit team was informed that "All staff are fully trained for the tasks to be carried out" (see also Section 8 of this report).

In accordance with Article 4.2 of Regulation (EC) No 882/2004 and Schedule 3 of the FSAI Service Contract, competent authorities are required to ensure that appropriate and properly maintained facilities and equipment are available for staff performing official controls.

Limerick Official Food Microbiology Laboratory/Public Health Laboratory informed the audit team that:

The laboratory has appropriate and properly maintained facilities and equipment for staff performing official controls. Minor equipment issues are dealt with by the clinical engineering department within the hospital services.

The audit team was informed that approval for replacement or new equipment is dependent on being sanctioned by hospital management where funding comes directly from the clinical services budget. A business case is required to be submitted by the laboratory where approval and funding is subject to competition with other clinical priorities and requests.

The audit team was informed that lack of funding and approval for certain projects has directly impacted on development of methods.

The audit team was informed that the laboratory information management system software (LIMS), although functional, requires updating to a newer package/version.

Immune magnetic separation (IMS) technology equipment, i.e. for the testing of *E. coli* O157 from food, water, or environmental samples, was due to be replaced in January 2015.

Limerick Official Food Microbiology Laboratory/Public Health Laboratory had received Polymerase Chain Reaction equipment on trial for *E. coli*/STEC confirmatory analysis. However, the laboratory had to send the equipment back in 2013, as they were not able to obtain funding for it. The laboratory stated that they had insufficient backing at a higher level in the organisation in order to make a stronger case for funding/approval.

In accordance with Regulation (EC) No 882/2004, competent authorities must ensure the impartiality, quality and consistency of official controls and that staff are free from conflict of interest. Recital (14) of Regulation (EC) No 882/2004 requires that official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality.

Procedures are in place in the Limerick Official Food Microbiology Laboratory/Public Health Laboratory which cover these requirements.

In addition to official controls, the laboratory also carries out a certain amount of private testing for clients in relation water analysis but does not conduct any in relation to food testing (FSAI pre-audit questionnaire).

The approach taken by Limerick Public Health Laboratory/Official Food Microbiology Laboratory to ensure that staff carrying out official controls are free from any conflict of interest in accordance with Regulation (EC) No 882/2004 Article 4.2 (b) requirements, is as follows (FSAI pre-audit questionnaire): "All laboratory staff are *bound by HSE policies and procedures, see The HSE Code of Standards and Behaviour Document 2.1, and as such freedom of conflict of interest is implied*".

## **4.2.2 Coordination and Planning of Official Controls**

### **(a) Sampling and Analysis**

**Arrangements are specified for the coordination of sampling and analysis between Environmental Health Service and Food Safety Laboratory Service in accordance with Section 3.2 of the FSAI Service Contract. Issues relating to coordination of sampling and analysis will primarily be dealt with through the EHO-Official Food Microbiology Laboratory-Public Analyst Laboratory Sampling groups in conjunction with the Authority.**

**In accordance with Clause 4.4 of the FSAI Service Contract – (official food control services to be provided) - The Food Safety Laboratory Service shall provide services for microbiological, chemical and other testing of foodstuffs for parameters including contaminants. Analysis shall be carried out in accordance with the Section 3 taking into account the relevant legislative requirements, guidelines and/or protocols.**

As part of the annual sampling programme agreed between the HSE, the Food Safety Laboratory Service and the FSAI at national level, 6,902 microbiological samples were required to be taken by the Environmental Health Service in 2014 and submitted to the relevant Food Safety Laboratory Service for testing, i.e. within one of the four HSE areas. These also form part of the HSE Work Programme outputs to be met by the Environmental Health Service/Food Safety Laboratory Service in accordance with the delivery of the FSAI Service Contract requirements.

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of microbiological testing from central to regional level and local levels, as part of the national sampling programme.

According to the Limerick Official Food Microbiology Laboratory/Public Health Laboratory (FSAI pre-audit questionnaire):

*“Total food numbers annually are based on the decision made by the Environmental Health Service and the FSAI. The laboratory is informed of this number and a schedule is formulated on this basis. Sampling schedule is discussed and agreed at the annual meeting with the Environmental Health Service. The type of food sampled is determined by the Environmental Health Service and the premises they are inspecting”.*

The audit team was provided with an example of a regional meeting for 2014 between the Limerick Official Food Microbiology Laboratory/Public Health Laboratory and Principal Environmental Health Officers areas, where laboratory and Environmental Health Service staff were present in order to coordinate sampling activities.

The timing and delivery of samples is agreed locally between Limerick Official Food Microbiology Laboratory/Public Health Laboratory and each of the Environmental Health Service Principal Environmental Health Officers areas.

The laboratory tested the sample numbers requested for analysis by the Environmental Health Service in both 2013 and 2014 and consequently, met the requirements of the FSAI work plan for service delivery.

**Table 2: Microbiological Testing of Samples Limerick Official Food Microbiology Laboratory/Public Health Laboratory (2013)**

<b>Sampling Activity/Reason</b>	<b>Number of Samples</b>
Routine	880
Repeat/Follow-up	20
Survey	131
Complaint	32
Import	0
Export	0
Control	12
Food Alert (RASFF)	0
Food Poisoning/Outbreak	82
Other - specify	0
<b>Total</b>	<b>1157</b>

For certain specialist microbiological parameters, individual Official Food Microbiology Laboratories have also developed expertise in certain areas and provide analytical typing services on a national basis, e.g.in the case of the Limerick Official Food Microbiology Laboratory/Official Food Microbiology Laboratory specialisations in the food area include analytical services for:

- Cronobacter
- *E. coli* in shellfish
- *E. coli* O157
- *E. coli* O26

The audit team was informed that in general, there were no deviations in testing performed for both 2013 and 2014, however on occasion there can be some flexibility as to when samples are received.

**(b) Coordination and Planning: National Meetings and Participation on Working Groups/Committees and Information Dissemination/Communication**

Limerick Official Food Microbiology Laboratory/Public Health Laboratory are represented on FSAI Working Groups/Committees and attend cross-agency meetings relevant to the performance of official controls and in accordance with FSAI Service Contract requirements.

The audit team also confirmed internal meetings, i.e. Public Health Staff meetings and Public Health TB Management Staff meetings take place where topics relevant to the coordination, planning and review of the performance of official controls are covered. The audit team was informed that team meetings take place roughly every six weeks and management meetings are at monthly intervals.

### 4.2.3 Sample Receipt, Handling and Analysis

#### (a) Sample Receipt, Handling and Analysis

***In accordance with Article 11.7 of Regulation (EC) No 882/2004 on methods of sampling and analysis, samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.***

The following Limerick Official Food Microbiology Laboratory/Public Health Laboratory procedures deal with the receipt and handling of samples on arrival at the laboratory:

- *Sample Handling FTM-SAMHAN Ver.4 (issue date 29/05/2014)* – deals with the handling of food samples on arrival at the laboratory
- *Sample Handling WTM-SAMHAN Ver.4 (issue date 06/06/2013)* – deals with the handling of water samples on arrival at the laboratory

The audit team confirmed that there is an effective system in place for identifying and tracking samples from receipt to testing, for samples analysed by the laboratory. Samples are labelled (which includes a barcode) and these are also attached to the EHO submission form (which accompanies the sample during transport), where a corresponding label is attached by the laboratory. The samples are also given a unique LIMS number on the IT system which also links with the labels on the sample and the Sample Request Form, thus ensuring full analysis traceability, i.e. for samples analysed by Limerick Official Food Microbiology Laboratory/Public Health Laboratory.

All Environmental Health Service food and water samples are directly handed into the laboratory by an EHO. The temperature of the cool box is recorded by Public Health Laboratory staff in the sample receipt book and entered into Labware. This temperature appears on the final report. The audit team was informed that: *“a comment is automatically generated if this temperature is outside the recommended ISO guideline transport temperatures, and the cool box and temperature monitoring device is the property of the Environmental Health Service and they are responsible for its maintenance and calibration”*.

Water samples from the hospital environment arrive by taxi.

The audit team confirmed that samples are in general, not rejected for temperature deviations.

The audit team was informed that the temperature of the sample on receipt is also recorded on the final report issued by the laboratory. The audit team reviewed one report issued by Limerick Official Food Microbiology Laboratory /Public Health Laboratory, where a high temperature of 10.5°C for a sample on receipt at the laboratory was recorded on the report, i.e. in accordance with the laboratory's procedures. This was flagged on the report issued, with the following remark also recorded: *“<<Please note ISO Transport Temperature Requirements>>”*.

Specific cases where there is an issue with the condition of the sample, e.g. sample leaking, or if insufficient sample has been received for testing, this is also recorded as a comment on the report.

#### (b) Timeframes for Analysis and Reporting of Results

The audit team was informed that the laboratory applies a seven to nine day target timeframe, for completing microbiological analysis and for reporting of results for Environmental Health Service food, water and environmental samples. The laboratory has not specified timeframes for analysing samples and reporting of results for all microbiological testing performed in its documented procedures.

A number of samples were reviewed for turnaround times, i.e. from the time the sample was taken to its receipt at the laboratory, and subsequently, the analysis performed and reporting of the result(s) to the client.

Most samples reviewed by the audit team were tested promptly and results were provided generally within a two-week timeframe. The audit team confirmed that on occasion however, particularly where subcontracted confirmatory analysis takes place, this can extend the total analysis turnaround timeframe, which in some cases can be up to or greater than four weeks.

**Table 3: Turnaround Times for Sample Analysis and Reporting Limerick Official Food Microbiology Laboratory/Public Health Laboratory Public Analyst Laboratory/Official Food Microbiology Laboratory**

Sample No.	Sample Type	Sample Date	Receipt Limerick Official Food Microbiology Laboratory/Public Health Laboratory	Analysis Date	First Report	Final Report
A	Complaint	26.3.14	26.3.14	26.3.14	2.4.14	N/A
B	Routine	23.10.13	23.10.13	23.10.13	22.11.13 <sup>1</sup>	27.11.13 <sup>2</sup>
C	Routine	12.11.14	12.11.14	12.11.14	24.11.14	N/A
D	Complaint	27.2.14	27.2.14	4.3.14	12.3.14	N/A

Note: Sample B – <sup>1</sup>first report date 22.11.13. <sup>2</sup>second report date 28.11.13 – due to additional outsourced confirmatory analysis performed by specialist reference laboratory

#### 4.2.4 Documented Procedures

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

**Recital (14) of Regulation (EC) No 882/2004 requires that official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality**

**Recital 17 of Regulation (EC) No 882/2004, laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated.**

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

The audit team looked at laboratory procedures and records relating to:

- Intake, handling and testing of samples
- Reporting of results, including the collection and reporting of data to the FSAI
- Selection and validation of methods, including the laboratory's scope of accreditation,
- Assessment an ongoing monitoring of method performance including internal quality control and participation in external proficiency testing schemes
- Internal and external audits
- Procedures for the control of non-conforming work
- Training of staff

A list of procedures was provided to the audit team in advance of the audit covering the above topics which included the laboratory's Quality Manual, Quality System SOPs, Foods Test Methods Manual and the Water Test Methods Manual.

The laboratory had procedures in place to verify the effectiveness of the official controls performed (see Section 10 of this report).

Consequently, the audit team's view is that procedures in place were sufficiently detailed and comprehensive in order to provide adequate instructions to staff to be followed for the performance of official controls and were being kept up-to-date, which meets the requirements of Regulation (EC) No 882/2004 and the FSAI's Service Contract requirements.

#### **4.2.5 Scope of Accreditation for the Performance of Official Controls**

***Competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with EN ISO/IEC 17025, i.e. 'General requirements for the competence of testing and calibration laboratories'***

***Service Contract Reference: Accreditation (4.3.1): The Food Safety Laboratory Service of the official agency shall be accredited by the Irish National Accreditation Board for appropriate functions and comply with ISO/IEC 17025:2005.***

***Such accreditation must be maintained and expanded in line with requirements and available resources and the requirements of Article 11 (2) and (3) of Regulation (EC) No 882/2004.***

***The official agency will provide the Authority with up to date information on the scope of their accreditation.***

The scope of accreditation for Limerick Official Food Microbiology Laboratory/Public Health Laboratory as listed on the INAB website:

<http://www.inab.ie/FileUpload/Testing/Public-Health-Laboratory-Limerick-096T.pdf> (Edition 26; 3/10/14)

Limerick Official Food Microbiology Laboratory/Public Health Laboratory provides updates to the FSAI regarding the maintenance and scope of the laboratory's accreditation to ISO 17025, in accordance with FSAI Service Contract requirements.

New tests added in 2013 were "Examination of waters for: TM 28.1 TVC- MF method, TM 30 Salmonella Detection and Confirmation, TM 34 TVC in purified water including dialysis quality water".

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As part of method development/service expansion, a method for Shiga toxin producing *E. coli* (STEC) by Polymerase Chain Reaction had been developed. However, due to lack of funding, the Polymerase Chain Reaction equipment was returned to the supplier.

The audit team confirmed that Limerick Official Food Microbiology Laboratory/Public Health Laboratory maintains and expands its accreditation in line with the requirements of Article 11 (2) and (3) of Regulation (EC) No 882/2004 and that the laboratory is accredited for the appropriate functions and range of tests in accordance with Regulation (EC) No 882/2004 and the requirements of the FSAI Service Contract.

At the time of the FSAI audit, the following methods were not currently included within the laboratory's scope of accreditation:

- *E. coli* O26 :Horizontal Method for Detection of *E. coli* O26 FTM -TM12.1
- The Isolation of Thermophilic *Campylobacter* species by Selective Enrichment in Water Samples WTM - TM29

The audit team was informed that no additional method development took place during 2014.

### 4.2.6 Performance of Official Controls -Testing/Analysis

#### (a) Method Selection

**Article 11 of Regulation (EC) No 882/2004 requires that sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or, (a) if no such rules exist, with internationally recognised rules or protocols, for those agreed in national legislation; or, (b) in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.**

**In accordance with Section 4.4.4, i.e. laboratory methods, of the FSAI Service Contract with the HSE - laboratories shall use methods that comply with Article 11 of Regulation (EC) No 882/2004. Laboratories performing the same analysis should use consistent methods to ensure comparability of results nationally.**

The approach taken by Limerick Official Food Microbiology Laboratory/Public Health Laboratory for the selection of methods is specified in Section 5.4.2 of the Quality Manual.

The audit team's view is that the approach taken by Limerick Official Food Microbiology Laboratory/Public Health Laboratory for selection of methods for the performance of official controls in general complies with Regulations 882/2004, 2073/2005, FSAI Guidance Note No. 3 and water testing requirements reviewed.

The audit team observed some variations regarding the selective and recovery media to be used for certain cultural methods, as recommended by the ISO standard's specification. However, these had been fully validated and had been demonstrated as fit for purpose, i.e.:

- *E. coli* media (rapid *E. coli* 2) used as an alternative to TBX media
- TSA media for *Listeria* used as an alternative to TSYEA media

**(b) Method Validation**

**Article 11.3 of Regulation 882/2004 requires that wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III (Characterisation of Methods of Analysis): *Methods of analysis should be characterised by the following criteria: (a) accuracy;(b) applicability (matrix and concentration range); (c) limit of detection;(d) limit of determination; (e) precision;(f) repeatability; (g) reproducibility; (h) recovery;(i) selectivity; (j) sensitivity; (k) linearity; (l) measurement uncertainty; (m) other criteria that may be selected as required.***

***In accordance with Recital 17 of Regulation 882/2004, laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated.***

The audit team confirmed that methods had been validated as part of the laboratory's accreditation to ISO 17025:2005 which also fulfilled the requirements of Regulation (EC) No 882/2004, 2073/2005 and FSAI Guidance Note No. 3 requirements, i.e.:

- Original Guidance Note No.3 (2001) and the interim Guidance Note No.3 (2007)
- FSAI Guidance Note No.3 Guidelines for the Interpretation of Results of Microbiological Testing of Ready-to-Eat Foods Placed on the Market (Revision 1)

Appropriate criteria had been applied in accordance with Annex III requirements of Regulation (EC) No 882/2004.

The methods for microbiological tests on food reviewed by the audit team, included:

- *Escherichia coli*: TM6 ISO 16649 - 2: 2001(pour plate using Rec2 agar - Association Française de Normalisation validation No.07-01 07-93)
- *Listeria* species including identification of *Listeria monocytogenes*: TM7E ISO 11290 part 2:1998/A1:2004 (spread/spiral)
- *Listeria* species including *Listeria monocytogenes*: TM7D ISO 11290 part 1:1996/A1:2004 (half fraser/full fraser enrichment)
- *Salmonella* species: TM8 ISO 6579: 2002/A1:2007 (RVS and MKTTn enrichment)
- Detection and Confirmation of: *Campylobacter* species: TM4 ISO 10272: 2006 (Bolton BrothEnrichment)
- Horizontal method for the Detection of *E.coli* O157 in foodstuffs TM 12 ISO 16654:2001(mTSB+N broth enrichment and IMS)
- *Escherichia coli*: Documented in-house methods based on: TM 15 ISO/TS 16649-3:2005(MPN) & ISO 7218:2007
- Horizontal method for the Detection of *E.coli* O26 in foodstuffs TM 12

In relation to the following accredited method, a validation report was not available on the day of the audit, notably for:

- *Listeria monocytogenes* and other *Listeria* species: Enumeration and Confirmation FTM -TM7

The audit team found that for all test methods that the uncertainty of measurement, limit of detection and limit of quantification was determined where relevant. Each method was deemed appropriate and approved by the Technical Manager.

All methods selected for use were either ISO standard procedures or alternative proprietary methods validated according to ISO 16140.

A documented review that validations conducted for the following methods, in order to confirm that they continued to be appropriate and fit for purpose, had not been recorded recently as having taken place, i.e. not since at least 2006, i.e. for:

- *Salmonella* species: Detection and Confirmation FTM - TM8
- *Campylobacter* species: Detection and Confirmation FTM -TM4
- *E. coli* O157: Horizontal Method for Detection of *E. coli* 0157 FTM -TM12

Although routine review of testing and trending of results takes place, a documented review that the uncertainty of measurement established for methods remains suitable/appropriate, was not being routinely recorded by the laboratory.

### **(c) Participation in External Quality Assurance - Proficiency Test Schemes**

The laboratory actively participates in external quality assurance, e.g. Public Health England, UK, Standard Scheme, the European Food Microbiology Legislation Scheme and the Shellfish Scheme.

The laboratory has a procedure in place to deal with any instances of laboratory results differing from those expected, where a detailed root cause analysis would be carried out in each case if required, i.e. as part of the laboratory's non-conforming work procedures.

The Limerick Official Food Microbiology Laboratory/Public Health Laboratory also carries out its own trending of results from external quality assurance participated in as part of the laboratory's own review of its performance.

Currently, there is no external quality assurance/proficiency test scheme available for the laboratory's *E. coli* O26 test method.

### **(d) Subcontracting of Methods of Analysis**

The approach taken by Limerick Official Food Microbiology Laboratory/Public Health Laboratory for the subcontracting of methods of analysis is as follows (FSAI pre-audit questionnaire):

- A National Reference Laboratory is used where available
- The Table Listing Laboratory Specialisations supplied by the FSAI is referred to for selecting appropriate labs for testing
- The criteria used for selection is that the laboratory is accredited for the test and is available to take samples

Limerick Official Food Microbiology Laboratory/Public Health Laboratory sends the following samples for further microbiological analysis:

- *Listeria* isolates are sent to the DAFM National Reference Laboratory (Backweston) for serological characterisation
- *Salmonella* isolates are sent to the National salmonella Reference Laboratory NSRL (Galway) for serological characterisation
- STEC (food and water) is sent to Cherry Orchard Public Health Laboratory/Official Food Microbiology Laboratory

*Vibrio parahaemolyticus* is sent to Sir Patrick Duns Public Analyst Laboratory/Official Food Microbiology Laboratory

#### **4.2.7 Performance of Official Controls: Reporting of Results and Data**

##### **(a) Reporting, Designation and Certification**

***In accordance with Section 4.4.5, i.e. reporting, designation and certification, of the FSAI Service Contract with the HSE - the Food Safety Laboratory Service shall agree and implement a consistent approach to the reporting of results of analysis at national level, including designation, observations, and certification; taking into account the requirements of Environmental Health Service and the Authority.***

***In accordance with Section 1.8, i.e. information systems, of the FSAI Service Contract with the HSE - the Official Agency Food Safety Laboratory Service shall transfer data on individual food samples taken under this contract electronically to the Authority from the laboratory LIMS. The FSAI shall collate and analyse national data based on the data transmissions from Food Safety Laboratory Service.***

***Schedule 2, 1.7 of the FSAI Service Contract with the HSE - refer to the annual work programme requirements regarding specific targets and measurable outcomes to be met, i.e. Appendix 1: Table 1 - 30th May 2014 - for Quarter 3 and 4 2014.***

In accordance with the annual work programme requirements for 2014, the following targets and measurable outcomes have been specified:

- Proposal for a standard suite of tests (Q2 2014)
- Standard approach to designation and reporting of results to be proposed including subcontracted tests and results (by end of 2014)

The audit team confirmed that a standard suite of tests had been agreed between the FSAI and the Official Food Microbiology Laboratories in 2014. An implementation date of 1<sup>st</sup> of January 2015 has been agreed by the Official Food Microbiology Laboratories.

The audit team confirmed that a draft document had been developed for the purposes of national designation of samples and reporting of results (Issue date 21.10.14), which had yet to be fully agreed by the Official Food Microbiology Laboratory group, before being implemented, i.e.:

*“Official Food Microbiological Laboratories National Policy on Interpretation of Microbiological Results and Designation of Official Control Food Samples”*

The audit team observed that Limerick Official Food Microbiology Laboratory/Public Health Laboratory do not apply an uncertainty of measurement to the result designation for Regulation (EC) No 2073/2005 quantitative testing.

##### **(b) Reporting of Data to the FSAI**

In accordance with the annual work programme requirements for 2014, the following targets and measurable outcomes have been specified:

- *Data and reports specified in Schedule 4 and Section 48(8) are submitted to the Authority (data@fsai.ie) in the format and timeframe specified in the schedule (by 3 weeks after reporting period and by 31st March each year) and other data reports where agreed*
- *LIMS – HSE Labs LIMS extracted data to be sent each week between Friday 1700 and Monday 0700, one week in arrears*
- *Labs to evaluate their LIMS compatibility with National Data Standards and EFSA’s SSD2 data standard with a view to planning updates to improve compliance*

The audit team confirmed that Limerick Official Food Microbiology Laboratory/Official Food Microbiology Laboratory had not yet configured their LIMS extracts for both sample and reporting designations in accordance with data transmissions/extracts format requested by the FSAI. Development on sample and report designations for methods was planned for early 2015.

The audit team was informed that: *“The LIMS extract includes subcontracted tests but not in the format required by the FSAI. A recent meeting of the Labware LIMS User Group and the FSAI agreed a format acceptable to both”.*

#### **4.2.8 Staff Performing Official Controls**

**Article 6 of Regulation 882/2004 requires that competent authorities shall ensure that all of its staff performing official controls: (a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. (b) keep up-to-date in their area of competence and receive regular additional training as necessary;**

**In accordance with Section 1.17 Continuing Professional Development in Food Safety Activities, of the FSAI Service Contract with the HSE - The official agency shall ensure that appropriate training, including induction training, is provided for staff performing official controls in line with Article 6(a) and Annex II, Chapter 1 of Regulation (EC) No 882/2004. Training records must be maintained for all staff performing official controls.**

The approach taken by Limerick Official Food Microbiology Laboratory/Public Health Laboratory regarding competency and training of staff, CPD, and maintenance of competency is as follows:

- The Laboratory's Training procedure is: *QSSOP – ST Training of New and Competent Medical/Food Scientists in the Public Health Laboratory Ver. 2.0 (issue date: 23/05/2012)*
- Staff training files are maintained
- Continued competence of staff performing official controls is addressed through Limerick Official Food Microbiology Laboratory/Public Health Laboratory's participation in external quality assurance schemes (a proficiency test rota was in place) and also as part of the laboratory's internal quality control tests performed by analysts
- Limerick Official Food Microbiology Laboratory/Public Health Laboratory stated that in recent years, funding and access to external training courses has been very restricted. The laboratory stated it was not able to attend a LabWare training course which would have been useful for its LIMS development and operation
- Where training is sanctioned, laboratory personnel attend seminars, workshops and other events relevant to their work
- The approach taken during audits, e.g. witness tests, looks at operational application of testing in accordance with procedures which confirms correct implementation of procedural requirements and verification that staff are appropriately trained

Assessments of training and competency are covered as part of the Limerick Official Food Microbiology Laboratory/Public Health Laboratory's own quality management system and as part of the laboratory's accreditation to ISO 17025:2005, where it is subject to routine assessments. The audit team's view is that training and competency of staff within laboratory is effective and meets the requirements of Regulation (EC) No 882/2004 and the FSAI Service Contract. Evidence of the performance of staff training and competence was seen via the results of external quality assurance, internal quality assurance, test witness audits, which were provided to the audit team.

#### **4.2.9 Interaction and cooperation with National Reference Laboratories**

***In accordance with Section 4.3 (Official Laboratories), of the FSAI Service Contract with the HSE - The Food Safety Laboratory Service shall function as 'official laboratories' as defined in Regulation (EC) No 882/2004 and as per procedures agreed with the Authority. They shall co-operate with the National Reference Laboratories for food testing in Ireland in the discharge of their functions under Article 33 of the Regulation and as per agreed protocols with the Authority.***

Official laboratories are required to cooperate with the relevant National Reference Laboratory in the fulfilment of the National Reference Laboratory role of coordinating the activities of official laboratories in their area of competence. Official laboratories for food are obliged under the service contract with the FSAI to co-operate with the National Reference Laboratories in the latter's discharge of their functions under Article 33 of the Regulation. This may include: providing all information to the National Reference Laboratory on request on the methods of analysis used in the official laboratory; requesting technical assistance from the National Reference Laboratory on methods of analysis within the National Reference Laboratories area of competence; providing information to the National Reference Laboratory on request on the comparative tests that the official laboratory is participating in.

To assist National Reference Laboratories in their role of monitoring and identifying emergent trends, official laboratories are required to provide information, samples/specimens, isolates to the National Reference Laboratory on request.

The list of National Reference Laboratories and official laboratories designated for official controls under Regulation (EC) No 882/2004 can be found at the following URL:

[http://www.fsai.ie/enforcement\\_audit/monitoring/national\\_official\\_labs.html](http://www.fsai.ie/enforcement_audit/monitoring/national_official_labs.html)

The audit team confirmed the following interaction with the National Reference Laboratories:

- Limerick Official Food Microbiology Laboratory/Public Health Laboratory has provided information to National Reference Laboratories when requested, e.g. completion of the Coordination of Activities questionnaire completed each year and returned to the DAFM National Reference Laboratories (Backweston)
- Requesting technical assistance from the National Reference Laboratories as required
- Limerick Official Food Microbiology Laboratory/Public Health Laboratory has provided Information to National Reference Laboratories on participation and performance in external quality assurance schemes when requested, e.g. completion of the Coordination of Activities questionnaire completed each year and returned to the DAFM National Reference Laboratories
- Limerick Official Food Microbiology Laboratory/Public Health Laboratory attends the annual meeting of official labs/FSAI and also partakes in *Listeria* external quality assurance scheme as requested by the DAFM National Reference Laboratory (Backweston)

In relation to subcontracting testing, Limerick Official Food Microbiology Laboratory/Public Health Laboratory fully cooperates with National Reference Laboratories, where:

- *Listeria* isolates are sent to the DAFM National Reference Laboratory (Backweston) for serological characterisation
- *Salmonella* isolates are sent to the National *Salmonella*, *Shigella* & *Listeria* Reference Laboratory in Galway for serological characterisation. This is not the National Reference Laboratory for food isolates<sup>3</sup>. The audit team was informed by Limerick Official Food Microbiology Laboratory/Public Health Laboratory that data are shared

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<sup>3</sup> The DAFM National Reference Laboratories have been designated for these functions in accordance with Ireland's National Control Plan 2012 – 16, i.e. as part of Regulation 882/2004, requirements.

between the National *Salmonella*, *Shigella* & *Listeria* Reference Laboratory and the National Reference Laboratory in Backweston

The laboratory highlighted the fact that currently there is no National Reference Laboratory for *Cronobacter*.

The audit team was satisfied that the laboratory was meeting its requirements regarding its interaction with the National Reference Laboratories.

#### **4.2.10 Verification and Review of the Performance of Official Controls**

**Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls**

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

**Article 4(6) of Regulation (EC) No 882/2004 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.**

The approach taken by the Limerick Official Food Microbiology Laboratory/Public Health Laboratory to ensure the effectiveness and appropriateness of official controls is via the following process, i.e. reference FSAI audit pre-audit questionnaire: participation in proficiency test schemes; training and competency of staff; procedures for approving/reporting results; internal audits; procedures for non-conforming work. According to the FSAI pre-audit questionnaire, Limerick Official Food Microbiology Laboratory/Public Health Laboratory: "As an accredited laboratory all these areas are addressed in our Quality Manual".

##### **(a) Internal Quality Assurance**

Appropriate and effective internal quality assurance is carried out by the Limerick Official Food Microbiology Laboratory/Public Health Laboratory in order to support test assurance. Positive controls and spiking of media were used to test media performance. A rota was in place to ensure staff participated in internal quality assurance tests as part of ongoing checks of staff competency and verification of method performance.

##### **(b) External Quality Assurance**

Verification of performance is also assessed via the laboratory's participation in external proficiency test schemes and their associated results. The audit team confirmed that the laboratory had satisfactory performance in proficiency test assessments and for those that did not achieve the expected result, these were adequately investigated to ensure that there was no impact on the quality of customer results relevant to the FSAI audit.

The Limerick Official Food Microbiology Laboratory/Public Health Laboratory also carries out its own trending of results from external quality assurance participated in, as part of the laboratory's own review of its performance.

The proficiency test schemes used and the laboratory's performance are also assessed by the DAFM (National Reference Laboratories in Backweston), on an annual basis. Reports for 2012 and 2013 deemed the laboratory's performance to be satisfactory in both years for the proficiency tests participated in.

### **(c) Internal and External Audits**

External audits are conducted by INAB as part of the laboratory's accreditation to ISO 17025:2005. The laboratory provided the audit team with the external audit reports for 2013 and 2014. A systematic and thorough approach was applied for closing out non-conformances highlighted during INAB surveillance assessments. Non-conformances had been cleared for both 2013 and 2014.

The audit team observed that an internal audit system as part of the HSE's compliance with the requirements of Article 4.6 of Regulation (EC) No 882/2004 is not in place. This also does not fully comply with Schedule 2 Section 1.20 of the FSAI Service Contract and Appendix 1 (1.20) of the FSAI work programme.

Internal audits are carried out as part of the laboratory's accreditation to ISO 17025:2005 covering the full remit of laboratory's accreditation. The internal audit schedule was fully up-to-date. Vertical audits cover all accredited tests over a three-year timeframe. Test witness audits are typically every two to three years.

All regularly used methods are subject to audits. The audit team observed however, that non-accredited tests may not be subject to internal audits. Consequently, the *E. coli* O26 test which was not yet fully accredited, was not subject to audits in 2013 and 2014.

The LabWare LIMS system is actively used to coordinate and monitor activities within the laboratory. Staff are informed of internal audits that must be completed; media performance and control of use, temperature of samples etc. are all flagged on the system.

### **(d) Meetings**

Regular internal meetings take place as part of the planning, coordination and review of official controls conducted and their performance, including a yearly management review. Team meetings take place every six weeks and management meetings take place at monthly intervals. The Limerick Official Food Microbiology Laboratory/Public Health Laboratory attends FSAI working groups and committees where up-to-date/relevant information is disseminated to staff within the laboratory.

### **(e) Reviews**

In general, effective performance of official controls is demonstrated via the laboratory's maintenance of its accreditation as part of its quality management system, in internal quality assurance, external quality assurance and internal and external audits, coordination and review meetings, training of staff and review of procedures, support and confirm the quality and consistency of official controls at the Limerick Official Food Microbiology Laboratory/Public Health Laboratory, i.e. subject to the following points below.

Although the audit team observed evidence of procedures to review aspects of the performance of accredited tests these were not formally documented. The audit team's view is that regular documented reviews should take place confirming that:

- Validations conducted by the laboratory for test methods, i.e. used as part of the performance of official controls, remain suitable and fully reflective of the testing performed

Uncertainty of measurements and limit of detections established for methods remain suitable/appropriate for the testing performed.

#### **4.2.11 Report of the Scientific Committee of the Food Safety Authority of Ireland**

***In accordance with Section 3 of the FSAI Service Contract, the Recommendations of the Authority's Scientific Committee report on sampling and microbiological examinations undertaken by the official agency will be reviewed and implemented in line with the actions agreed with the Authority and the official agency.***

***“Review of the Sampling and Microbiological Examinations undertaken by the Health Service Executive, 2007 and 2008” <https://www.fsai.ie/WorkArea/DownloadAsset.aspx?id=11989>***

The audit team confirmed that progress had been made with closing out the scientific committees recommendations. Consequently, at the time of the audit, several recommendations had been fully closed, whilst others were a work in progress. Coordination of their close-out was being managed by the FSAI's through on-going communications and via regular meetings with the Environmental Health Service and Food Safety Laboratory Service.

### **4.3 Audit Findings: The Health Service Executive, Public Health Laboratory (Official Food Microbiology Laboratory), Galway University Hospital**

#### **Report of the Audit of Compliance of Official Food Microbiology Laboratories with Regulation (EC) No 882/2004 and Service Contract Obligations**

##### **4.3.1 Organisation and Structure of Official Controls**

###### **(a) Designation of Official Control Laboratories**

***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.***

***Article 12 of Regulation (EC) No 882/2004 requires competent authorities to designate accredited laboratories to carry out analyses of samples taken in the context of official controls.***

The Public Health Laboratory, Galway University Hospital has been designated as an accredited laboratory, i.e. to ISO 17025:2005, for the performance of official controls in accordance with the requirements of Regulation (EC) No 882/2004. The Public Health Laboratory operates as an Official Food Microbiology Laboratory for food control testing as part of the Food Safety Laboratory Service in accordance with the FSAI Service Contract with the Health Service Executive.

The main part of the laboratory's activities involves the analyses of samples that have been taken by environmental health officers, as part of their supervisory function and in the course of their visits to food business operators. These samples are taken to support inspection as part of monitoring and surveillance programmes or as part of the investigation of an outbreak, incident, food alert or consumer complaint.

In addition to the analyses of official control samples, the laboratory also performs some private testing for clients.

**(b) Organisational Structure of the Food Safety Laboratory Service (Official Food Microbiology Laboratories) within the HSE**

***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.***

***Section 4.3 of the FSAI Service Contract: The Food Safety Laboratory Service (Food Safety Laboratory Service) shall function as 'official laboratories' as defined in Regulation (EC) No 882/2004 and as per procedures agreed with the Authority.***

As part of the Food Safety Laboratory Service, the HSE has nine official laboratories involved in microbiological and chemical analysis of food.

These include three Public Analyst Laboratories and seven Official Food Microbiology Laboratories.

The Galway University Hospital Public Health Laboratory is not linked to any Public Analyst Laboratory and operates independently as an Official Food Microbiology Laboratory within the HSE.

The Food Safety Laboratory Service does not have a national structure within the HSE for coordination and management of the group nationally, which does not meet the requirements of Section 4.2 of the HSE Service Contract with the FSAI (HSE Service Contract Revision 2 – 14/01/2013).

“Both parties to the service contract recognise the importance of establishing an integrated management system for the Food Safety Laboratory Service within the framework of the official agency that will provide for the overall management and coordination of the Food Safety Laboratory Service. Both parties to the contract agree that this should be established as a matter of priority”.

The audit team is aware that this issue has been highlighted over a number of years by the FSAI to the HSE management at national level without resolution to-date.

**(c) Operational Criteria Requirements**

***Article 4 of Regulation (EC) No 882/2004 requires Member States to lay down operational criteria for the competent authorities performing official controls.***

***Article 4(2) The competent authorities shall ensure:***

- ***Staff performing controls are free of any conflict of interest,***
- ***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***

***Article 4(4) Competent authorities shall ensure impartiality, consistency and quality of official controls at all levels***

***Article 4(6) Competent authorities shall carry out internal audits or may have external audits carried out In accordance with Schedule 2, 1.1, of the service contract the official agency will provide staff and all resources required to ensure delivery of service outputs/activity required.***

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The audit team was informed that the LIMS software, although functional, requires updating to a newer package/version.

According to Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) the laboratory has adequate staff to provide for the FSAI Service Contract requirements.

The audit team was informed that the laboratory was not allowed to take on temporary or agency staff when staffing numbers had been impacted by leave, e.g. maternity leave in 2012 and 2013.

The approval/funding for the filling of staff positions is dependent on being sanctioned by hospital management. The audit team was informed that the lack of resources has impacted on progress with method development and extension of scope for certain methods, e.g. for Norovirus testing.

The audit team was informed that funding for replacement or new equipment also comes directly from the clinical services budget and is also dependent on hospital management approval. A lack of funding and approval for certain projects poses challenges for the laboratory and directly impacts on the development and expansion of methods used by the laboratory.

The Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) stated that they felt that they were not represented at a high enough level at hospital management meetings in order to compete with other clinical requests and influence outcomes for their benefit.

**Table 1: Overview of Resources in Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory)**

Grade /Title (31 <sup>st</sup> Dec 2013)	Staff - All Duties		Staff Engaged in any Food Control Activity		
	Total number of posts ( <sup>1</sup> WTE)	Total number of posts filled ( <sup>1</sup> WTE)	Total (number of staff)	Total number of posts filled ( <sup>1</sup> WTE)	<sup>2</sup> Total number of posts ( <sup>1</sup> WTE)
Consultant Microbiologist	1	0.3	5	0.3	1
Senior Medical Scientist	5	2	2	2	5
Medical Scientist	4	3.8	4	3.3	4
Laboratory Secretary	1	1	2	1	1
<b>Total</b>	<b>11</b>	<b>7.1</b>	<b>13</b>	<b>6.6</b>	<b>11</b>

\*Note: Staff - All Duties is used to record the total number of staff in the laboratory.

<sup>1</sup> WTE- Whole Time Equivalent

<sup>2</sup> No. of posts identified in 1<sup>st</sup> Service Contract + no. of additional approved posts (filled + unfilled)

Staff training and competency is extensively covered as part of the Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) quality management system and procedures operated by the

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laboratory and as part of their accreditation to ISO 17025:2005(E). The audit team was informed that all staff are fully trained and competent for the tasks to be carried out (see also Section 8 of this report).

In accordance with Article 4.2 of Regulation (EC) No 882/2004 and Schedule 3 of the FSAI Service Contract, competent authorities are required to ensure that appropriate and properly maintained facilities and equipment are available for staff performing official controls.

Despite the laboratory facilities not being ideal, Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) informed the audit team that in their view, they are adequate to perform the testing required under Regulation (EC) No 882/2004 and the FSAI Service Contract in an efficient and effective manner and continue to meet accreditation requirements.

In accordance with Regulation (EC) No 882/2004, competent authorities must ensure the impartiality, quality and consistency of official controls and that staff are free from conflict of interest. Recital (14) of Regulation (EC) No 882/2004 requires that official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality. Procedures are in place in the Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) which covers these requirements and are reviewed for their effectiveness (see Sections 4 and 10 of this report for further details).

In addition to official controls, the laboratory also carries out a certain amount of private testing for clients. The laboratory does not currently perform any testing as part of the provision of health certificates for exports or otherwise.

The approach taken by Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) to ensure that staff carrying out official controls are free from any conflict of interest in accordance with Regulation (EC) No 882/2004 Article 4.2 (b) requirements is as follows (FSAI pre-audit questionnaire):

According to Section A4 of the quality manual (Issue No:6):

*“Conflicts of interest that may arise between staff members and samples submitted are reported by the staff member to senior management and the analyst may not take any part in the testing or reporting of the food or water sample”.*

*“All staff of the Public Health Microbiology Laboratory are employees of the HSE Western Region and prior to commencing employment must sign a confidentiality agreement (CAG 1), stating that all information in relation to the identification, analysis and reporting of Public Health Microbiology Laboratory samples is confidential and may not be discussed or relayed outside of the Public Health Microbiology Laboratory except in an official capacity”.*

*“The agreement also requests staff to declare any conflicts of interest that might arise from samples submitted for any testing to a member of senior management. Signed copies of this confidentiality agreement are retained in the training file of each staff member (Ref: 4.1.4)”.*

According to Section A.7 of the quality manual (Issue No:6):

*“It is the policy of this laboratory to avoid involvement in any activity that would diminish confidence in its competence, impartiality, judgement and operational activity”.*

### **4.3.2 Coordination and Planning of Official Controls**

#### **(a) Sampling and Analysis**

***Arrangements are specified for the coordination of sampling and analysis between Environmental Health Service and Food Safety Laboratory Service In accordance with Section 3.2 of the FSAI service contract. Issues relating to coordination of sampling and analysis will primarily be dealt with through the EHO-Official Food Microbiology Laboratory-Public Analyst Laboratory sampling groups in conjunction with the Authority.***

***In accordance with clause 4.4 of the FSAI Service Contract – (Official Food Control Services to be provided) - The Food Safety Laboratory Service shall provide services for microbiological, chemical and other testing of foodstuffs for parameters including contaminants. Analysis shall be carried out in accordance with the Section 3 taking into account the relevant legislative requirements, guidelines and/or protocols.***

As part of the annual sampling programme, agreed between the HSE, the Food Safety Laboratory Service and the FSAI at national level, 6,902 microbiological samples were required to be taken by the Environmental Health Service in 2014 and submitted to the relevant Food Safety Laboratory Service for testing, i.e. within one of the four HSE areas. These also form part of the HSE Work Programme outputs to be met by the Environmental Health Service/Food Safety Laboratory Service in accordance with the delivery of the FSAI Service Contract requirements.

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of microbiological testing from central to regional level and local levels as part of the national sampling programme.

The timing and delivery of samples is agreed locally between Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) and each of the Environmental Health Service Principal Environmental Health offices and these schedules were also provided.

The laboratory tested the sample numbers requested for analysis by the Environmental Health Service in both 2013 and 2014 and consequently, met the requirements of the FSAI work plan for service delivery.

**Table 2: Microbiological Testing of Samples Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) (2013)**

Sampling Activity/Reason	Number of Samples
Routine	514
Repeat/Follow-up	36
Survey	136
Complaint	12
Import	0
Export	0
Control	3
Food Alert (RASFF)	0
Food Poisoning/Outbreak	2
Other - specify	26
Total	729

The audit team was informed that in general, there no deviations in testing performed for both 2013 and 2014.

For certain specialist microbiological parameters, individual Official Food Microbiology Laboratories have also developed expertise in certain areas and provide analytical typing services on a national basis, e.g. in the case of the Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory), specialisations in the food area include analytical services for:

- Norovirus, Shigella testing (both yet to be developed and validated)
- *E. coli* in shellfish (already an accredited method)

**(b) Coordination and Planning: National Meetings and Participation on Working Groups/Committees and Information Dissemination/Communication**

Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) is represented on FSAI Working Groups/Committees and attends cross-agency meetings relevant to the performance of official controls and in accordance with FSAI Service Contract requirements.

The audit team also confirmed regular internal meetings, i.e. including scheduled quarterly staff meetings, and an annual review meeting take place at Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory), where topics and information relevant to coordination, planning and review of the performance of official controls are discussed.

### 4.3.3 Sample Receipt, Handling and Analysis

#### (a) Sample Receipt, Handling and Analysis

***In accordance with Article 11.7 of Regulation (EC) No 882/2004 on methods of sampling and analysis, samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity.***

The Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) Quality Manual Section U (Issue No: 6) and the Laboratory Procedures Manual (Section 12), deals with the receipt and handling of samples on arrival at the laboratory.

According to Section U of the quality manual (Issue No.6):

*“It is the policy of the Public Health Microbiology Laboratory to ensure that the procedures undertaken for the receipt, handling, protection, storage, retention and disposal of all test items submitted ensures as far as possible the integrity of the item”.*

The audit team confirmed that there is an effective system in place for identifying and tracking samples from receipt to testing for samples analysed by the laboratory. Samples are labelled (which includes a barcode) and these are also attached to the EHO submission form (which accompanies the sample during transport) where a corresponding label is attached by the laboratory. The samples are also given a unique LIMS number on the IT system which also links with the labels on the sample and the Sample Request Form, thus ensuring full analysis traceability, i.e. for samples analysed by Galway University Hospital.

Samples are either directly handed in to the laboratory by an EHO or arrive by courier/taxi that has been organised for their transport.

Where the sample is dropped in by the EHO, Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) requires them to record the temperature of the sample on the Food Safety Laboratory Service Sample Request Form (Sample Request Form) on receipt at the laboratory. Where samples are dropped in by courier/taxi, Galway University Hospital staff record the temperature of the sample on the Sample Request Form.

According to Section U of the quality manual (Issue No:6):

*“If a condition is identified which might have a significant effect, or invalidate the results obtained, the customer is advised of any potential problem, and analysis is carried out based on the customer’s instruction”.*

*“If the laboratory decides to test the sample then the condition of the sample on receipt will be indicated as ‘Unsatisfactory’ on the Final Report”.*

The audit team confirmed that the condition and temperature of samples received are also entered on the laboratory’s LIMS system.

The audit team confirmed that samples are not in general, rejected for temperature deviations. The audit team observed instances where the temperatures of samples at intake to laboratory were missing on certain reports issued by the laboratory.

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### (b) Timeframes for Analysis and Reporting of Results

Timeframes for testing and reporting have not been defined in the laboratory's procedures.

In general, prompt testing and reporting was observed. The audit team confirmed that on occasion reporting of microbiological results by the laboratory to the client can take longer primarily due to the fact that the subcontracted confirmatory analysis can extend the total analysis turnaround timeframes.

**Table 3: Turnaround Times for Sample Analysis and Reporting Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory)**

Sample No.	Sample Type	Sample Date	Receipt Galway University Hospital	Analysis Date	First Report	Final Report
A	Routine	11.3.14	12.3.14	12.3.14	18.3.14	N/A
B	Routine	1.4.14	1.4.14	7.4.14	15.5.14	N/A
C	Complaint	17.1.14	21.1.14	21.1.14	28.1.14 <sup>1</sup>	5.2.14 <sup>2</sup>
D	Survey	9.6.14	9.6.14	9.6.14	17.6.14 <sup>1</sup>	27.6.14 <sup>2</sup>
E	Routine	12.5.14	12.5.14	12.5.14	19.5.14 <sup>1</sup>	13.10.14 <sup>2</sup>
F	Complaint	9.6.14	9.6.14	9.6.14	17.6.14 <sup>1</sup>	27.6.14 <sup>2</sup>

Note: Sample C – <sup>1</sup>first report date 28.1.14 issued with *S. aureus* Toxin Gene (SATG) detection <sup>2</sup>second report date 5.2.14 – due to (SATG) confirmation PHE Colindale. Temperature on receipt at laboratory not stated and temperature not stated on report. Sample considered as satisfactory on report.

Note: Sample D – <sup>3</sup>first report date 17.6.14 issued with *S. aureus* Toxin Gene (SATG) detection <sup>4</sup>second report date 27.6.14 – due to (SATG) confirmation PHE Colindale. Temperature on receipt at laboratory not stated and not stated on report.

Note: Sample E – Report reissued on 13/10/14 due the fact that the sample reason was not a survey sample butt was a routine test. This was not reported to the FSAI. Temperature on receipt at laboratory stated on Sample Request Form and recorded on report.

Note: Sample F – Condition of sample on receipt recorded as unsatisfactory on Report.

Evidence was seen in the case of an unsatisfactory sample, i.e. sample F above, that the condition of the sample was also recorded as such on the report issued by the laboratory.

For non-accredited tests performed by Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory), these are flagged with an asterisk on the audit report, e.g. Report for Sample F for yeast and moulds.

#### **4.3.4 Documented Procedures**

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

**Recital (14) of Regulation (EC) No 882/2004 requires that official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality.**

**Recital 17 of Regulation (EC) No 882/2004, laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated.**

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

The audit team looked at laboratory procedures and records relating to:

- Intake, handling and testing of samples
- Reporting of results, including the collection and reporting of data to the FSAI
- Selection and validation of methods, including the laboratory's scope of accreditation
- Assessment and ongoing monitoring of method performance including internal quality control and participation in external proficiency testing schemes
- Internal and external audits
- Procedures for the control of non-conforming work
- Training of staff

The laboratory did not have a procedure in place to deal with positives that could potentially arise from private testing but agreed to put one in place to deal with these cases.

The laboratory had procedures in place to verify the effectiveness of the official controls performed (see Section 10 of this report). Consequently, the audit team's view is that procedures in place were sufficiently detailed and comprehensive in order to provide adequate instructions to staff to be followed for the performance of official controls and were being kept up-to-date, which meets the requirements of Regulation (EC) No 882/2004 and the FSAI Service Contract requirements.

The laboratory regularly reviews its uncertainty of measurement for all methods used. According to Section R.3 of the quality manual (Issue No:6):

*"An estimation of the uncertainty of measurement of the test result is calculated by the laboratory at least annually, to ensure that this uncertainty value still reflects the conditions in the laboratory such as staffing and equipment in use".*

*"Calculations for the uncertainty of measurement for each test parameter for which the laboratory is accredited will be calculated on an annual basis using data from laboratory quality control testing".*

The laboratory regularly reviews its methods and procedures used. According to Section R.1 of the quality manual (Issue No:6):

*"The laboratory will review all methods at least annually to ensure that they, where appropriate, reflect the current version of the standard or reference on which they are based".*

At the annual review meeting for 2014 the audit team verified that the “*Suitability of Policies and Procedures Report for 2013*” was also reviewed and discussed.

#### **4.3.5 Scope of Accreditation for the Performance of Official Controls**

***Competent authorities may only designate laboratories that operate and are assessed and accredited in accordance with EN ISO/IEC 17025, i.e. ‘General requirements for the competence of testing and calibration laboratories’***

***Service Contract Reference: Accreditation (4.3.1): The Food Safety Laboratory Service of the Official Agency shall be accredited by the Irish National Accreditation Board for appropriate functions and comply with ISO/IEC 17025:2005.***

***Such accreditation must be maintained and expanded in line with requirements and available resources and the requirements of Article 11 (2) and (3) of Regulation (EC) No 882/2004.***

***The official agency will provide the Authority with up to date information on the scope of their accreditation***

The scope of accreditation for Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) as listed on the INAB website:

<http://www.inab.ie/FileUpload/Testing/Public-Health-Microbiology-Laboratory-Galway-097T.pdf>

Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) provides updates to the FSAI regarding the maintenance and scope of the laboratory’s accreditation to ISO 17025 in accordance with FSAI Service Contract requirements.

The audit team confirmed that the laboratory maintains and expands its accreditation in line with the requirements of Article 11 (2) and (3) of Regulation (EC) No 882/2004 and that the laboratory is accredited for the appropriate functions and range of tests in accordance with Regulation (EC) No 882/2004 and the requirements of the FSAI Service Contract.

During 2014 two changes took place to the laboratory’s Scope of Accreditation:

- Method 11 – Enumeration of Micro-organisms by pour plate @ 30°C is now based on ISO 4833-1:2013
- Method 11a – Enumeration of Micro-organisms by surface plating @ 30°C is now based on ISO 4833-2:2013

No method development took place in 2014.

The laboratory has intentions to extend their current scope of accreditation to included detection and enumeration of Norovirus testing in foodstuffs.

The audit team was informed that Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) have access to Polymerase Chain Reaction equipment for virus testing in the Galway University Hospital clinical microbiology laboratory.

At the time of the FSAI audit, a number of non-accredited tests had yet to be included in the laboratories scope and schedule of accreditation.

These included analysis for yeast and moulds.

Four yeast and mould samples had been tested in 2012 and three in 2014. The audit team confirmed that the FSAI section 48(8) annual report for Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) for 2013 had not reported the 2012 results.

#### **4.3.6 Performance of Official Controls -Testing/Analysis**

##### **(a) Method Selection**

**Article 11 of Regulation (EC) No 882/2004 requires that sampling and analysis methods used in the context of official controls shall comply with relevant Community rules or, (a) if no such rules exist, with internationally recognised rules or protocols, for those agreed in national legislation; or, (b) in the absence of the above, with other methods fit for the intended purpose or developed in accordance with scientific protocols.**

**In accordance with section 4.4.4, i.e. laboratory methods, of the FSAI service contract with the HSE - Laboratories shall use methods that comply with Article 11 of Regulation (EC) No 882/2004. Laboratories performing the same analysis should use consistent methods to ensure comparability of results nationally.**

The approach taken by Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) for the selection of methods is as follows:

*“The laboratory has selected the methods contained in its scope of accreditation, on the basis that the method is suitable for the testing required, and has met the approval of the customer”.*

Methods chosen are either:

- ISO standard methods
- ISO standard methods that have been modified by the laboratory
- Approved methods being used by other official organisations, e.g. UK Environment agency
- In-house methods developed by the laboratory

##### Standard methods – food laboratory

*“Standard methods used by the food laboratory are internationally recognised standard methods published as BS EN Standards, BS ISO Standards or BS EN ISO Standards”.*

##### Standard methods – water laboratory

*“Standard methods used in the water laboratory are national standard methods published by the UK Environment Agency as a national standard method or ISO methods”.*

##### Standard methods with laboratory modifications

*“Certain standard methods or national standard methods have been modified by the laboratory, in an effort to improve the performance of the method”.*

*“These modifications have been validated by the laboratory and the validations approved by INAB”.*

In-house methods (non-standard)

*“These methods are based on published documented methods. These are methods which have been chosen by the laboratory because of their suitability for use, and usually because no standard method is available for the specific test”.*

For the test methods reviewed by the audit team, the selection by the laboratory of these methods to be used for the performance of official controls, in general complies with Regulations (EC) No 882/2004, 2073/2005, FSAI Guidance Note No. 3 and water testing requirements.

The audit team observed some variations regarding the selective and recovery media to be used for certain cultural methods, as recommended by the ISO standard's specification, however these had been fully validated and had been demonstrated as fit for purpose.

*E.coli* media not TBX (rapid *E.coli* 2).

For *Listeria* confirmation not using TSYEA, i.e. Using Columbia Agar with addition of Sheep's blood for haemolysis confirmation

A number of amendments have been made to the ISO method by the laboratory for *Campylobacter* testing.

A longer resuscitation step is used for one *E.coli* testing method to improve recovery and performance.

**(b) Method Validation**

**Article 11.3 of Regulation (EC) No 882/2004 requires that Wherever possible, methods of analysis shall be characterised by the appropriate criteria set out in Annex III (Characterisation of Methods of Analysis): *Methods of analysis should be characterised by the following criteria: (a) accuracy;(b) applicability (matrix and concentration range); (c) limit of detection;(d) limit of determination; (e) precision;(f) repeatability; (g) reproducibility; (h) recovery;(i) selectivity; (j) sensitivity; (k) linearity; (l) measurement uncertainty; (m) other criteria that may be selected as required.***

***In accordance with Recital 17 of Regulation 882/2004, laboratories involved in the analysis of official samples should work in accordance with internationally approved procedures or criteria-based performance standards and use methods of analysis that have, as far as possible, been validated.***

The audit team confirmed that methods had been validated as part of the laboratory's accreditation to ISO 17025:2005, which also fulfilled the requirements of Regulation (EC) No 882/2004, 2073/2005 and FSAI Guidance Note No.3 requirements, i.e. original Guidance Note No. 3 (2001), and the interim Guidance Note No. 3 (2007), FSAI *Guidance Note No. 3 Guidelines for the Interpretation of Results of Microbiological Testing of Ready-to-Eat Foods Placed on the Market (Revision 1)*.

Appropriate criteria had been applied in accordance with Annex III requirements of Regulation (EC) No 882/2004.

The methods for microbiological tests on food reviewed by the audit team included:

- Detection of *Salmonella* species – SOP No 12 ( ISO 6579:2002+A1:2007)
- Detection of *Listeria monocytogenes* – SOP No 22b ( ISO 11290-2:1998 + A1: 2004)
- Enumeration of *Listeria monocytogenes* and *Listeria* species – SOP No 22b ( ISO 11290-2:1998 + A1: 2004)
- Detection of thermotolerant *Campylobacter* species – SOP No 5 ( ISO 10272-1:2006)
- Enumeration of *E.coli* in shellfish using the MPN technique – SOP No 20 (based on DD ISO/TS 16649-3:2005 Part 3 Enumeration of *E.coli* in raw molluscs by the Multiple Tube Technique)

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- Enumeration of Coliforms and *E.coli* by membrane filtration with in-house confirmation using chromogenic agar – SOP No W2 - (based on MDW 2009) part 4-section A

The approach taken by Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) for the selection of methods is as follows:

*“To achieve an objective validation the laboratory uses a combination of the following validation techniques appropriate to the requirements of the validation procedures”:*

Techniques include:

- Use of reference materials
- Comparison of results with other validated/standard methods
- Use of inter-laboratory comparisons, e.g. external quality control samples
- Systematic assessment of the factors influencing the result
- Assessment of the uncertainty of the results based on theoretical principles and practical experience of the method

*“Results obtained from one or a combination of the above techniques are then used to obtain a range and accuracy for values generated by the validated method. This will include the uncertainty of the test results, the detection limit of the method and any other factors such as selectivity of the method, repeatability, robustness from external influences, interference by sample matrix etc., that might be significant for the intended purpose of the method or that is relevant to the needs of the customer”.*

Procedures for the validation of methods and the criteria that must be met in order for the validation to be acceptable are documented in Section 8 of the Laboratory Procedures Manual.

The audit team found that for all test methods reviewed, the uncertainty of measurement, limit of detection and limit of quantification were determined where relevant. Each method was deemed appropriate and approved by the Technical Manager. The uncertainty of measurement, limit of detection and limit of quantification were acceptable in all methods reviewed. Methods were regularly reviewed for fitness for purpose and validation reports updated as required. All methods selected for use were either ISO standard procedures or alternative proprietary methods validated according to ISO 16140.

### (c) Participation in External Quality Assurance - Proficiency Test Schemes

The laboratory actively participates in external quality assurance, e.g. Public health England, UK, Standard Scheme, and the European Food Microbiology Legislation Scheme and the Shellfish Scheme and results were satisfactory. In relation to any instances of laboratory results differing from those expected, a root cause analysis was carried out in each case. The investigation(s) took place in order to confirm that there has been no impact on test results from the laboratory. The audit team's view in relation to one of the proficiency test result investigations reviewed is that the evidence supporting the conclusion that there had been no impact on test results should be more clearly documented.

### (d) Subcontracting of Methods of Analysis

According to Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) the approach taken for subcontracting of methods of analysis is as follows (FSAI pre-audit questionnaire):

- *“The laboratory does not subcontract tests to other laboratories for which it is accredited. Additional tests, e.g. Staphylococcal toxin testing, Salmonella serotyping etc. are sent to an outside laboratory”.*

- *“The laboratory will normally select a laboratory on the basis that it is a reference laboratory for the service provided, e.g. PHE Colindale London, DAFM Laboratories, Backweston”.*
- *“The criteria used is that the laboratory should be a reference laboratory and be accredited to perform the testing required”.*

The audit team observed however, that in a number of instances *Listeria* isolates were not sent to the DAFM National Reference Laboratory in Backweston, which is designated for this function, in accordance with Ireland’s National Control Plan 2012 – 16, i.e. as part of Regulation 882/2004, requirements. Similarly, Staphylococcal toxin confirmatory samples are also sent to the PHE in Collindale but are not sent to the DAFM National Reference Laboratory in Backweston, designated for this function.

*Salmonella* isolates were being sent to the National Salmonella Reference Laboratory in Galway for confirmation.

#### **4.3.7 Performance of Official Controls: Reporting of Results and Data**

##### **(a) Reporting, designation and certification**

***In accordance with section 4.4.5, i.e. reporting, designation and certification, of the FSAI Service Contract with the HSE - the Food Safety Laboratory Service shall agree and implement a consistent approach to the reporting of results of analysis at national level, including designation, observations, and certification; taking into account the requirements of Environmental Health Service and the Authority.***

***In accordance with Section 1.8, i.e. Information Systems, of the FSAI Service Contract with the HSE - the Official Agency Food Safety Laboratory Service shall transfer data on individual food samples taken under this contract, electronically to the Authority from the laboratory LIMS. The FSAI shall collate and analyse national data based on the data transmissions from Food Safety Laboratory Service.***

***Schedule 2, 1.7 of the FSAI Service Contract with the HSE - refer to the annual work programme requirements regarding specific targets and measureable outcomes to be met, i.e. Appendix 1: Table 1 - 30th May 2014 - for Quarter 3 and 4 2014.***

In accordance with the annual work programme requirements for 2014, the following targets and measureable outcomes have been specified:

- Proposal for a standard suite of tests (Q2 2014)
- Standard approach to designation and reporting of results to be proposed including subcontracted tests & results (by end of 2014)

The audit team confirmed that a standard suite of tests had been agreed between the FSAI and the Official Food Microbiology Laboratories in 2014. An implementation date of 1<sup>st</sup> of January 2015 has been agreed by the Official Food Microbiology Laboratories.

At the time of the audit, a draft document had been developed between the FSAI and the seven Official Food Microbiology Laboratories for the designation of samples and interpretation of results. However, it had still yet to be fully agreed and signed off for implementation.

*“Official Food Microbiological Laboratories National Policy on Interpretation of Microbiological Results and Designation of Official Control Food Samples”.*

The audit team observed that Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) does not apply an uncertainty of measurement to the result designation for Regulation (EC) No 2073/2005 quantitative testing.

### **(b) Reporting of Data to the FSAI**

In accordance with the annual work programme requirements for 2014, the following targets and measurable outcomes have been specified:

- *Data and reports specified in Schedule 4 and Section 48(8) are submitted to the Authority (data@fsai.ie) in the format and timeframe specified in the schedule (by three weeks after reporting period and by 31st March each year) and other data reports where agreed*
- *LIMS – HSE Labs LIMS extracted data to be sent each week between Friday 1700 and Monday 0700, one week in arrears*
- *Labs to evaluate their LIMS compatibility with National Data Standards and EFSA's SSD2 data standard with a view to planning updates to improve compliance*

The audit team confirmed that Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) had configured their LIMS extracts for sample designation but had yet to complete this for report designation.

The LIMS extracts however, do not always include subcontracted tests, e.g. the subcontracting of test isolates to the National Reference Laboratory.

#### **4.3.8 Staff Performing Official Controls**

***Article 6 of Regulation (EC) No 882/2004 requires that competent authorities shall ensure that all of its staff performing official controls:(a) receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner. (b) keep up-to-date in their area of competence and receive regular additional training as necessary;***

***In accordance with Section 1.17 Continuing Professional Development in Food Safety Activities, of the FSAI Service Contract with the HSE - The official agency shall ensure that appropriate training, including induction training, is provided for staff performing official controls in line with Article 6(a) and Annex II, Chapter 1 of Regulation (EC) No 882/2004. Training records must be maintained for all staff performing official controls.***

The approach taken by Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) regarding competency and training of staff, CPD and maintenance of competency is as follows:

- The laboratory has specified competency requirements under: "Section P - Personnel" of the quality manual.
- A detailed training manual is in place for assuring the quality of test results
- Continued competence of staff performing official controls is addressed through Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) participation in external quality assurance schemes (a proficiency test rota was in place) and also as part of the laboratory's internal quality control tests performed by analysts
- Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) stated that in recent years, funding and access to external training courses has been very restricted. The laboratory stated it was not able to attend a LabWare training course which would have been useful for its LIMS development and operation
- Where training is sanctioned, laboratory personnel attend seminars, workshops and other events relevant to their work
- The approach taken during audits, e.g. witness tests, looks at operational application of testing in accordance with procedures which confirms correct implementation of procedural requirements and verification that staff are appropriately trained

Assessments of training and competency are covered as part of the Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) own quality management system, and as part of the laboratory's accreditation to ISO 17025:2005, where it is subject to routine assessments. The audit team's view is that training and competency of staff within laboratory are effective and meet the requirements of Regulation (EC) No 882/2004 and the FSAI Service Contract. Evidence of the performance of staff training and competence was seen via the results of external quality assurance, internal quality assurance, test witness audits which were provided to the audit team.

#### **4.3.9 Interaction and cooperation with National Reference Laboratories**

***In accordance with Section 4.3 (official laboratories), of the FSAI Service Contract with the HSE - The Food Safety Laboratory Service shall function as 'official laboratories' as defined in Regulation (EC) No 882/2004 and as per procedures agreed with the Authority. They shall co-operate with the National Reference Laboratories for food testing in Ireland in the discharge of their functions under Article 33 of the Regulation and as per agreed protocols with the Authority.***

Official laboratories are required to cooperate with the relevant National Reference Laboratory in the fulfilment of the National Reference Laboratory role of coordinating the activities of official laboratories in their area of competence. Official laboratories for food are obliged under the service contract with the FSAI to co-operate with the National Reference Laboratories in the latter's discharge of their functions under Article 33 of the Regulation. This may include: providing all information to the National Reference Laboratory on request on the methods of analysis used in the official laboratory; requesting technical assistance from the National Reference Laboratory on methods of analysis within the National Reference Laboratories area of competence; providing information to the National Reference Laboratory on request on the comparative tests that the official laboratory is participating in.

To assist National Reference Laboratories in their role of monitoring and identifying emergent trends, official laboratories are required to provide information, samples/specimens, isolates to the National Reference Laboratory on request.

The list of National Reference Laboratories and official laboratories designated for official controls under Regulation (EC) No 882/2004 can be found at the following URL:

[http://www.fsai.ie/enforcement\\_audit/monitoring/national\\_official\\_labs.html](http://www.fsai.ie/enforcement_audit/monitoring/national_official_labs.html)

The audit team confirmed the following interaction with the National Reference Laboratories:

- The laboratory has completed the annual DAFM Listeria National Reference Laboratory Limerick 14/52 Questionnaire on methods in use for the detection and enumeration of *Listeria monocytogenes*
- The laboratory did not require assistance from the National Reference Laboratory in relation to methods
- The laboratory took part in the *Listeria* External Quality Assurance Scheme run by the DAFM National Reference Laboratory for Listeria held in September 2014
- The laboratory used the DAFM Dairy Science Laboratory National Reference Laboratory for Coagulase Positive Staphylococci for Staphylococcal enterotoxin detection during a rapid alert in 2014

Galway University Hospital does not however, send *Listeria monocytogenes* isolates to the designated DAFM National Reference Laboratory in Backweston.

Galway University Hospital is not in general, sending Staphylococcal toxin confirmatory samples to the designated DAFM National Reference Laboratory in Backweston.

The DAFM National Reference Laboratories have been designated for these functions for food analysis in accordance with Ireland's National Control Plan 2012 – 16, i.e. as part of Regulation (EC) No 882/2004 requirements.

#### **4.3.10 Verification and Review of the Performance of Official Controls**

**Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls**

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

**Article 4(6) of Regulation (EC) No 882/2004 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.**

The approach taken by the Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) to ensure the effectiveness and appropriateness of official controls is via the laboratory's accreditation to ISO 17025:2005 and specifically in relation to the following sections contained in the laboratory Quality Manual:

- Proficiency test schemes
- Training and competency
- Reporting of results
- Internal audits
- Non-conforming Work
- Method validation
- Handling of test items
- LIMS
- Service to customer

##### **(a) Scope of Accreditation**

The laboratory takes a proactive approach to review and extend their scope of accreditation, i.e. to include additional methods and matrices, as required and where feasible, which in order to meets the requirements of Regulation (EC) No 882/2004, 2073/2005 and the FSAI Service Contract, e.g.:

- Work is currently in progress towards developing a Polymerase Chain Reaction-based method for Norovirus detection and enumeration in foodstuffs

##### **(b) Internal Quality Assurance**

INAB audits confirmed that appropriate internal quality assurance is carried out by the Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) to support test assurance.

### **(c) External Quality Assurance**

Verification of performance is assessed via the laboratory's active participation in external proficiency test schemes and their associated results. The audit team confirmed that the laboratory performed well in most of these and for those that did not achieve the expected result, these were in general, fully investigated to ensure that there was no impact on the quality of customer results, relevant to the FSAI audit.

The proficiency test schemes used, the level of laboratory participation and their performance are also assessed by the DAFM (National Reference Laboratories in Backweston) on an annual basis. Reports for 2012 and 2013 deemed the laboratory's performance to be satisfactory in both years.

### **(d) Internal and External Audits**

External audits are conducted by INAB as part of the laboratory's accreditation to ISO 17025:2005. The laboratory provided the audit team with the external audit reports for 2013 and 2014. A systematic and thorough approach was applied for closing out non-conformances highlighted during INAB surveillance assessments. Non-conformances had been cleared for both 2013 and 2014.

The audit team observed that an internal audit system as part of the HSE's compliance with the requirements of article 4.6 of Regulation (EC) No 882/2004, is not in place. This also does not fully comply with Schedule 2 Section 1.20 of the FSAI Service Contract and Appendix 1 (1.20) of the FSAI Work Programme.

Internal audits are carried out as part of the laboratory's accreditation to ISO 17025:2005. Vertical, horizontal and test witness audits are conducted for regularly used methods and an audit schedule was in place. The audit team confirmed however, for non-accredited tests/less frequently used methods, e.g. in the case of yeast and mould testing, these were not subject to the same degree of internal or external audit verification.

### **(e) Meetings**

Regular internal meetings take place as part of the planning, coordination and review of official controls conducted and their performance, including a yearly management review. Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) attends FSAI working groups and committees where up-to-date/relevant information is disseminated to staff within the laboratory.

### **(f) Review of Procedures**

The laboratory's procedures are also reviewed on a scheduled basis in order to confirm and reflect their continued suitability and effectiveness. The Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) Quality Manual and Procedures also deal with impartiality and conflict of interest.

In general, the audit team's view is that effective performance of official controls is demonstrated via the laboratory's maintenance of its accreditation as part of its quality management system, in internal quality assurance, external quality assurance and internal and external audits, coordination and review meetings, training of staff and review of procedures, support and confirm the quality and consistency of official controls at the Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory).

## **4.3.11 Report of the Scientific Committee of the Food Safety Authority of Ireland**

***In accordance with Section 3 of the FSAI Service Contract, the Recommendations of the Authority's Scientific Committee report on sampling and microbiological examinations undertaken by the Official Agency will be reviewed and implemented in line with the actions agreed with the Authority and the official agency.***

**“Review of the Sampling and Microbiological Examinations undertaken by the Health Service Executive, 2007 and 2008”:** <https://www.fsai.ie/WorkArea/DownloadAsset.aspx?id=11989>

The audit team confirmed that progress had been made with closing out the scientific committees recommendations. Consequently, at the time of the audit several recommendations had been fully closed, whilst others were a work in progress. Coordination of their close-out was being managed by the FSAI through on-going communications and via regular meetings with the Environmental Health Service and Food Safety Laboratory Service.

## **5. AUDIT CONCLUSIONS and RECOMMENDATIONS**

### **5.1 Audit Conclusions**

In general, an effective system of official controls is in place for microbiological testing/analysis performed and results reported by the Official Food Microbiology Laboratories audited, subject to a number of findings identified in this report that require corrective action to be taken (these are captured in the corrective action plan hyperlinked in Section 6 of this report).

A structured approach for the organisation, planning, coordination and delivery of official controls was verified as generally being in place in the three Official Food Microbiology Laboratories audited.

In addition, a number of recommendations are also made in Section 5.2 of this report.

All findings should be disseminated nationally to ensure that corrective actions and opportunities for improvement identified are shared across all Official Food Microbiology Laboratories to ensure their effective implementation.

### **5.2 Audit Recommendations**

A number of recommendations are suggested which should be considered by the Food Safety Laboratory Service/FSAI (and Environmental Health Service where applicable), in order to address additional opportunities for improvement identified to the current system of official controls in place.

- A central management structure and single contact point within the HSE should be put in place for the co-ordination, management and representation of the Food Safety Laboratory Service group nationally.
- Laboratory samples were not in general, being rejected for temperature deviations. This should be reviewed by the FSAI/Environmental Health Service/Food Safety Laboratory Service as a group, in order to ensure that there are no implications or consequences for guaranteeing the validity of samples analysed and results reported. Regulation (EC) No 882/2004 article 11.7 requires that, “Samples must be handled and labelled in such a way as to guarantee both their legal and analytical validity”.

- The audit team observed differences regarding the selection of and participation in, external proficiency testing schemes used by Official Food Microbiology Laboratories audited. It is recommended that selection of proficiency test schemes and level of participation should be reviewed by the FSAI/Official Food Microbiology Laboratory as a group, i.e. with possible National Reference Laboratory input, in order to ensure a consistent approach to proficiency tests nationally. Consideration could also be given to include Official Food Microbiology Laboratory participation in the same proficiency test rounds for comparative purposes and to assist National Reference Laboratories in their oversight role.
- A standard approach to application of uncertainty of measurement to the results being reported for microbiological analysis of samples should be addressed in the draft FSAI/Official Food Microbiology Laboratory working document: *“Official Food Microbiological Laboratories National Policy on Interpretation of Microbiological Results and Designation of Official Control Food Samples”*.

## **6. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION**

Audit findings requiring corrective action are listed in the corrective action plan hyperlinked below. All findings identified during this audit should be disseminated nationally to ensure that corrective actions and opportunities for improvement identified are implemented across all Official Food Microbiology Laboratories.

[Hyperlink to Corrective Action Plan](#)





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