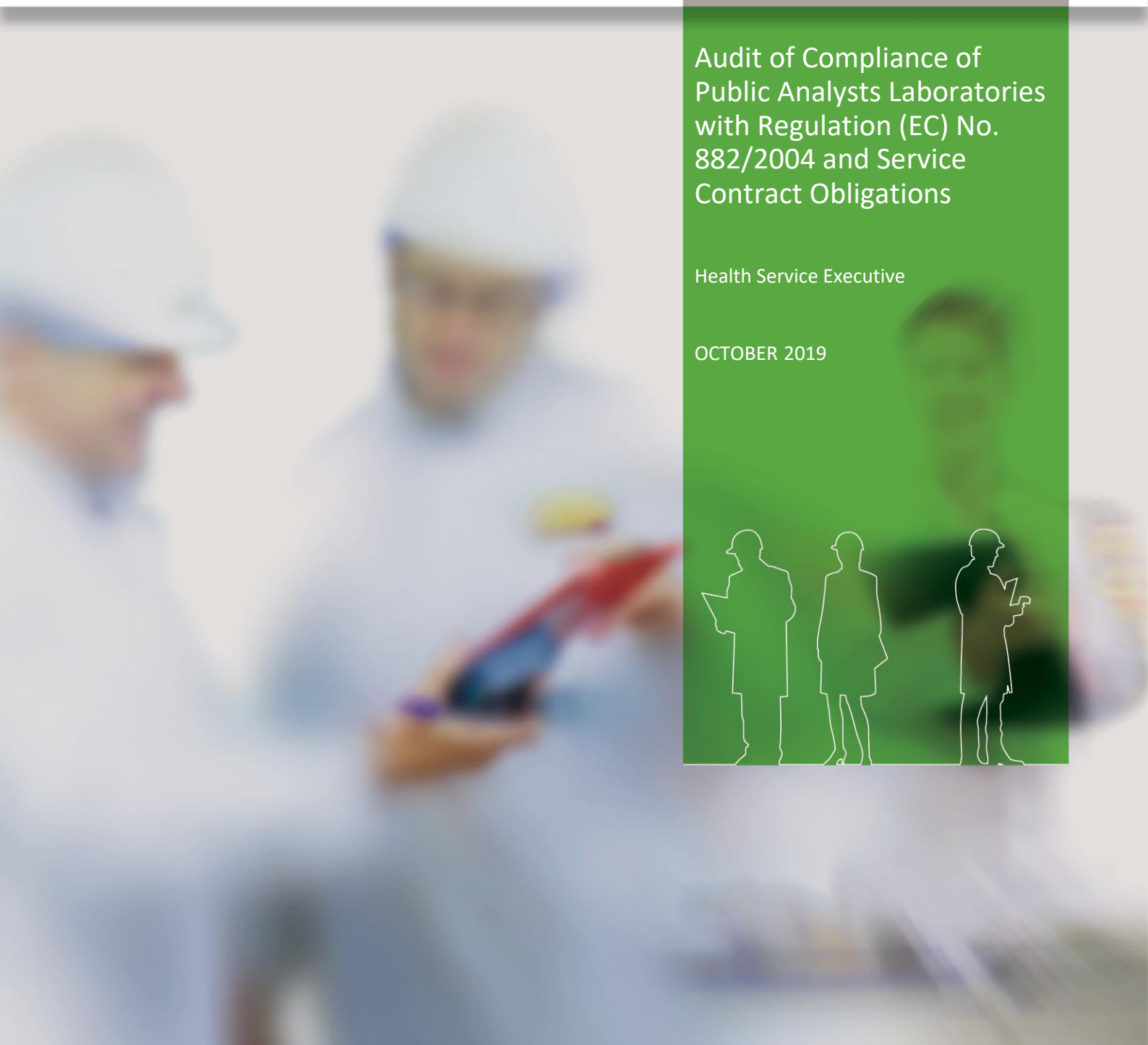
Food Safety
AUTHORITY OF IRELAND

AUDIT REPORT

Audit of Compliance of Public Analysts Laboratories with Regulation (EC) No. 882/2004 and Service Contract Obligations

Health Service Executive

OCTOBER 2019



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1. Glossary

AAS	Atomic Absorption Spectrophotometer
CEN	European Committee for Standardisation
EFSA	European Food Safety Authority
EHS	Environmental Health Service
ELISA	Enzyme Linked Immunosorbent Assay
EQA	External Quality Assurance (schemes)
ESPGHAN	European Society for Paediatric Gastroenterology, Hepatology and Nutrition
EURL	European Union Reference Laboratory
FCM	Food Contact Material
FERA	UK Food and Environment Research Agency
FSAI	Food Safety Authority of Ireland
FSLS	Food Safety Laboratory Service
FVO	Food and Veterinary Office
GC-MS	Gas Chromatography Mass Spectrometry
HPLC	High Performance Liquid Chromatography
HSE	Health Service Executive
ICP-MS	Inductively Coupled Plasma Mass Spectrometry

INAB	Irish National Accreditation Board
ISO	International Organization for Standardization
IT	Information Technology
LC-MS	Liquid Chromatography Mass Spectrometry
LIMS	Laboratory Information Management System
LOD	Limit of Detection
LOQ	Limit of Quantification
NRL	National Reference Laboratory
PAL	Public Analyst's Laboratory
PCR	Polymerase Chain Reaction
PT	Proficiency Test (schemes)
S.I.	Statutory Instrument
SLA	Service Level Agreement

2. Executive Summary

The Food Safety Authority of Ireland is responsible for the enforcement of all food legislation in Ireland, which is primarily carried out through service contracts with official agencies. As part of its legal mandate, the Food Safety Authority of Ireland is required to verify that the system of official controls is working effectively.

This audit was carried out to assess compliance of the HSE Public Analyst's Laboratories with Regulation (EC) No. 882/2004 and service contract obligations. This included assessment of the effectiveness, appropriateness and suitability of official controls performed. There are three Public Analyst's Laboratories in Ireland: Dublin, Galway and Cork, all three were audited.

As part of the preparation for this audit, a review of relevant information and data held within the FSAI relating to official controls carried out by the Public Analyst's Laboratory Service of the HSE was conducted. Following this review, each of the three Public Analyst's Laboratories completed a pre-audit questionnaire. The on-site component consisted of meetings with laboratory and management personnel and the audit of relevant activities. In order to demonstrate fulfilment of requirements, access was provided on all three sites to the laboratory information management system (LIMS), procedures, and records. These included internal and external audit reports, details regarding the Public Analyst's Laboratories' participation in proficiency testing and the associated results, validation reports for methods used, and interactions with European and National Reference Laboratories(NRLs). Following the audit of each Public Analyst's Laboratory, a report of preliminary findings was sent to the laboratory.

A structured approach to the delivery of the official control testing under the requirements of the service contract was noted in each of the three Public Analyst's Laboratories. The maintenance of the accreditation to ISO 17025:2005, participation in External Quality Assurance schemes as well as internal and external audits contributed to the effective performance of official controls. At the time of the audit each of the three laboratories had commenced preparations for assessment of compliance by the Irish National Accreditation Board (INAB) with the requirements of ISO 17025:2017 and Regulation (EU) 2017/625 on official controls and other official activities.

Flexible scope was in use in two out of the three laboratories. The effective use of the laboratory management process as a management tool in the Dublin PAL was identified as a strength by the audit team. Differences were observed in the manner in which rejected samples are logged in the laboratories and this may need to be reviewed in order to improve consistency across the service. The absence of a national structure within the HSE, for co-ordination and management of the Food Safety Laboratory Service(FSLS), hampers consistency and progression within the Public Analyst Laboratory service at a national level. The implementation of a national structure is a requirement of the FSAI - HSE service contract and had also been identified as not being in place during a previous FSAI audit of the Official Food Microbiology Laboratories; yet remains outstanding.

3. Introduction

3.1. Audit objective

The primary objective of the audit was to assess compliance of HSE Public Analyst's Laboratories with Regulation (EC) No. 882/2004 and Service Contract obligations. This included assessment of the effectiveness, appropriateness and suitability of official controls performed.

3.2. Audit scope

During the audit the FSAI confirmed whether the HSE Public Analyst's Laboratories official control activities complied with the audit criteria specified in section 3.3 of this report, in relation to the testing/analysis and reporting systems in place (i.e. in accordance with the FSAI Service Contract, and Regulation (EC) No 882/2004 and associated legislation).

3.3. Audit Criteria and Reference Documents

- Food Safety Authority of Ireland Act, 1998 (S.I. No 29 of 1998), as amended.
- Service Contract between FSAI and Health Service Executive
- Regulation (EC) No 882/2004 on Official Controls Performed to Ensure Verification of Compliance with Feed and Food law, Animal Health and Animal Welfare Rules, as amended
- The National Control Plan for Ireland for the period from 1st January 2012 to 31st December 2017
- 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
- Relevant aspects of ISO 17025 that also relate to the FSAI Service Contract and Regulation (EC) No. 882/2004
- Overview of Findings in relation to laboratories arising from audits conducted by Santé Directorate F, Health and Food Audits and Analysis (previously known as the Food and Veterinary Office (FVO)

3.4. Audit methodology

This audit of official controls was undertaken as part of the planned programme of audits undertaken by the FSAI,using the audit procedures documented in the FSAI's Business Management System. These procedures describe the FSAI's audit obligations defined in Schedule 5 of the Service Contract between the FSAI and the HSE, and in accordance with the requirements of Regulation (EC) No 882/2004, Commission Decision 2006/677/EC, and Section 48(9) of the Food Safety Authority of Ireland Act, 1998, as amended.

As part of the preparation for this audit, a review of relevant information and data held within the FSAI relating to official controls carried out by the Public Analyst's Laboratory Service of the HSE was conducted. Following this review, each of the three Public Analyst's Laboratories in Cork, Dublin and Galway completed a pre-audit questionnaire in respect of information relevantto the audit.

An evaluation plan describing the audit process and approach – including the scope, objectives, criteria and audit team – was then sent to each of the three Public Analyst's Laboratories. During the audit the FSAI team confirmed whether the HSE Public Analyst's Laboratories' official control activities complied with the audit criteria specified in section 3.3 of this report, in relation to the testing/analysis and reporting systems in place.

In preparation for this audit, FSAI also met with the Irish National Accreditation Board (INAB) to confirm the scope of ISO 17025:2005[1] accreditation audits performed by them. During the audit, the audit team did not presume that all aspects of legislation and FSAI service contract requirements were automatically covered by the laboratory's accreditation to ISO 17025:2005. The audit team required evidence that these aspects were being fulfilled as per the requirements of the service contract.

The on-site audit consisted of meetings with the laboratory management personnel as well as the audit of relevant activities. In order to demonstrate fulfilment of requirements, access was provided to laboratory information management system (LIMS), procedures, and records. These included internal and external audit reports, details regarding the Public Analyst's Laboratories' participation in proficiency testing and the associated results, validation reports for methods used, and details of interactions with European National Reference Laboratories.

A closing meeting was held following the completion of the on-site audit activities with each Public Analyst's Laboratory. A report of the preliminary audit findings was sent to each of the laboratories audited.

[1] ISO 17025:2005: General requirements for the competence of testing and calibration laboratories

4. Audit Findings

4.1. Dublin Public Analyst's Laboratory

4.1.1. Designation of official control laboratories

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities (CAs) 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.

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

Sir Patrick Duns, Public Analyst Laboratory (PAL), which is accredited to ISO 17025:2005, has been designated as an official laboratory for the performance of official controls in accordance with the requirements of Regulation (EC) No. 882/2004. The PAL operates as part of the FSLS within the FSAI Service Contract with the Health Service Executive (HSE).

The majority of the laboratory's official control activities involve the analysis of samples that have been taken by enforcement officers. These samples are taken to support inspections; as part of monitoring and surveillance programmes or as part of the investigation of an outbreak, incident, food alert or consumer complaint. There is a small amount of private testing for clients (8 samples between January and October 2018).

4.1.2. Organisational structure of the Food Safety Laboratory Service (PALs) within the HSE

Recital (16) of Regulation (EC) No 882/2004 requires that 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 4.2 of the FSAI service contract: National Management System for the Food Safety Laboratory Service

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. The Official Agency will review the existing management structures and implement an appropriate national structure for the Food Safety Laboratory Service during the term of the contract.

There is no national structure within the HSE, for co-ordination and management of the FSLS, which does not meet the requirements of section 4.2 of the HSE service contract with the FSAI (this finding is outstanding from a previous audit of the Official Food Microbiology Laboratories in 2014 by FSAI).

Laboratory management within the Dublin PAL have raised this issue with the HSE management (the 2014 audit report was made available to HSE management).

4.1.3. Operational criteria requirements

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

Article 4(2) requires that 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) requires that competent authorities shall ensure impartiality, consistency and quality of official controls at all levels.

Article 4(6) requires that competent authorities shall carry out internal audits or may have external audits carried out.

In accordance with Schedule 2, section 1.1, of the service contract the Official Agency will fulfil its obligations regarding food safety as agreed with the Authority under the terms of this contract.

As part of the response to the pre-audit questionnaire Dublin PAL informed the FSAI audit team that following the filling of current vacancies there will be adequate staff to provide the service required. However, the projected work increases due to Brexit and Regulation (EU) 2017/625 on official controls and other official activities may further impact staff resources and additional staff may be required. The laboratory has raised these issues with HSE management. In recent years the laboratory has been in a position to replace the long-term use of agency staff with permanent staff. Steps are in progress to fill current vacancies due to recent retirements/redeployments. Recently, the laboratory has also received approval to again recruit 2 agency staff (1 office, 1 chemistry) to deal with short term non-availability of staff (e.g. maternity leave). The laboratory manages its staff resources to ensure that staff assigned to particular areas are matched to the workload.

Table 1: Overview of resources in Dublin PAL

Grade /Title	Total number of posts (includes those being filled at time of audit)	Whole time equivalent (WTE) for each post
Public Analyst	1	1
Deputy Public Analyst[1]	2	2
Executive Analytical Chemist	12	11.91
Executive Analytical Chemist (Microbiology)	3	3.66
Executive Analytical Chemist (Microbiology (Acting))	1	1
Senior Laboratory Technician Chemistry	4	3.05
Senior Laboratory Technician Microbiology[2]	2	2
Laboratory Technician Chemistry[3]	14	12.62
Laboratory Technician Microbiology	7	6.15
Clerical Officers[4]	5	3.67
Medical Laboratory Aide	1	0.9
Total	**52**	**47.96**

Comments on Table 1:
[1] One post (1.0 WTE) being processed by recruitment at the time of the audit
[2] One post (1.0 WTE) being processed by recruitment at the time of the audit
[3] One post (1.0 WTE) being processed by recruitment at the time of the audit
[4] One post (0.5 WTE) being processed by recruitment at the time of the audit

Staff training and competency is addressed in the quality management system (QMS) and as part of the accreditation to ISO 17025:2005.

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.

Management representatives from the Dublin PAL informed the audit team that:

The laboratory suffered during the recession from a lack of capital resources to replace ageing equipment. This has led to increased downtime due to breakdowns and non-availability of particular instruments for extended periods. This has adversely impacted both on turnover times and method development. Some progress has been made to alleviate this situation in the past two years and the laboratory expects to continue to procure new equipment. However, some equipment is particularly expensive. For example, a single Mass Spectrometer instrument could require spending the totality of a year's capital allocation considering the capital allocation levels of the past two years.

The laboratory also indicated that it needs a capital budget to fund the acquisition of entirely new equipment, i.e. not based on a concept of replacement. Innovative approaches to capital funding will be required for the future. Extension of work as is required under Regulation (EU) 2017/625 on official controls and other official activities will also lead to a requirement for additional equipment.

Slow progress is being made in efforts to upgrade the laboratory IT system and associated Laboratory Information Management System (LIMS) and Empower software systems. Until this is complete, the laboratory management believe it remains vulnerable to IT failures. The audit team were advised that the LIMS system upgrade should be complete by the end of Quarter 1 2019.

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.

Dublin PAL operates an integrated quality management system for all functions within the laboratory (microbiology and chemistry), which is accredited to ISO 17025:2005.

In relation to the management of potential staff conflict of interest, Dublin PAL ensures:

1. Staff members acknowledge their reading of the HSE code of standards and other HSE policies related to these matters.
2. The matter is addressed in the staff contract of employment.
3. The laboratory addresses the issue in the Quality Manual at section 4.5.1 (d). The manual is reissued every year and all staff members are required to acknowledge reading it.
4. A statement on conflict of interest is included in all Service Level Agreements (SLAs).
5. The avoidance of conflict of interest is part of the traditional ethos of the PAL system and, as such, becomes part of the culture of the laboratory.

4.1.4. Sampling and analysis

Arrangements are specified for the coordination of sampling and analysis between EHS and FSLS 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 EHS-PAL sampling groups in conjunction with the Authority. The official agency shall ensure national implementation of sampling and analysis decisions.

In accordance with clause 4.4.1 of the FSAI Service Contract, 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.

The audit team confirmed that there was a structured and well-organised approach for the coordination and planning of chemical testing from central to regional level and local levels, as part of the national sampling programme. However, there are some difficulties in getting the necessary samples to fulfil the testing programme on an annual basis.

It was noted, as part of the review of the Non-analysable Samples log, that a number of samples submitted for Food Contact Material (FCM) analysis were not appropriate. In each case, the individual sampling officers were notified by the analyst regarding the unsuitability of the sample. The notes on the regional sampling plan regarding sample type(s) for FCM testing include a clear description of the sample type(s) required. However, this could be further emphasised with sampling officers and may need to be reviewed periodically to see if improvements can be made.

4.1.5. Documented procedures

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

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, requires that 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) of Regulation (EC) No 882/2004 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 examined laboratory procedures and records relating to:

- The laboratory's scope of accreditation
- The intake, handling and testing of samples
- The selection and validation of methods
- The assessment and on-going monitoring of method performance, including participation in external proficiency testing schemes
- Internal and external audits
- Subcontracted testing

- Procedures for the control of non-conforming work
- Customer requirements and communications.

Dublin PAL had operational controls and procedures in place to verify the effectiveness of the official controls performed. The procedures reviewed were sufficiently detailed and comprehensive in order to provide adequate instructions to staff to be followed for the performance of official controls; were regularly reviewed and met the requirements of Regulation (EC) No 882/2004 and the FSAI service contract requirements.

The laboratory management team meetings were utilised as an effective management tool to ensure that any issues arising in the laboratory in relation to official control work were being addressed and communicated to staff.

4.1.6. Laboratory scope of accreditation

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'

Section 4.4.2 of the Service Contract regarding accreditation requires that 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 requirements of Article 11 (2) and (3) of Regulation (EC) No. 882/2004. Over the duration of this contract, the Food Safety Laboratory Service will work toward expanding accreditation for all the methods used by the laboratories when testing Official control samples in the scope of this contract in so far as is possible.

The Official Agency will provide the Authority with up to date information on the scope of their accreditation.

Dublin PAL was, at the time of the audit, accredited to ISO 17025:2005 and the laboratory advised that their next planned Irish National Accreditation Board (INAB) audit scheduled for Quarter 1 2019 would be to the ISO 17025:2017 version of the standard.

The current scope of accreditation for Dublin PAL is listed on the INAB website: https://www.inab.ie/Directory-of-Accredited-Bodies/Laboratory-Accreditation/Testing/Public-Analyst-s-Laboratory-Dublin.html. The published scope for Dublin PAL, at the time of the on-site activity, was used as the basis for audit activities.

However, at the time of the FSAI audit, a number of additional tests (accredited at the last INAB audit) had yet to be included in the laboratory's scope and schedule of accreditation. This was due to an IT issue on INAB's part which has since been resolved.

Dublin PAL has been operating under flexible scope[2] since 2016; and has used flexible scope to facilitate the extension of accredited tests by matrix, analyte and range. The use of flexible scope is covered in SOP PALA 30. The

[2] Flexible scope of accreditation means that a laboratory may claim accreditation for testing not currently included in the defined scope of accreditation, without specific prior approval by INAB. Flexible scope may be granted to a laboratory following a successful audit of the laboratory's systems and processes. See INAB explanatory document regarding flexible scope.

use of flexible scope was reviewed in relation to three tests, (arsenic in fruit and vegetable juices and bread, artificial sweeteners in chocolate powder, and sulphur dioxide (SO_2) in beverages), and was found to be satisfactory.

In relation to the testing for sulphur dioxide and sulphites as an additive, it was noted that the Limit of Quantification (LOQ) for the method was set at 10 ppm. This is the legal limit above which sulphur dioxide and sulphites must be declared (in terms of total SO_2) from an additive as well as an allergen labelling viewpoint. The audit team acknowledges that Dublin PAL is testing products with limits set in the region of 50 ppm. The audit team notes that a European Food Safety Authority (EFSA) scientific opinion from 2016 on the re-evaluation of sulphur dioxide and the sulphites notes improved sensitivity for a number of methods being employed to analyse sulphites.[3]

The audit team confirmed that Dublin PAL 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 882/2004/2044 and the requirements of the FSAI service contract. The Dublin PAL are conscious of the fact that all methods will require accreditation under the new official controls Regulation (EU) 2017/625 and work has commenced in this regard on method development and accreditation for the following methods/matrices:

- Mineral oils in food, Erucic acid and plasticisers (Gas Chromatography Mass Spectrometry (GC-MS)), Ergot alkaloids, Pyrrolizidine alkaloids and Opium alkaloids Liquid Chromatography Mass Spectrometry (LC-MS). Dublin PAL stated that it was their intention to have Erucic acid and plasticisers accredited in 2019, as part of working towards the accreditation requirements in Regulation (EU) 2017/625 on official controls and other official activities.
- Delta 9 Tetrahydrocannabinol – this test is not yet accredited, but a proficiency test has been carried out and Dublin PAL stated that it was their intention to submit the results to INAB for accreditation of the method.
- Chlorate and Perchlorate are still in method development.
- Tropane alkaloids – accredited for cereals and baby foods.
- Alternaria toxins – Dublin PAL are part of the European Committee for Standardisation (CEN) working group to develop a method for Alternaria mycotoxins and will participate in the next inter-laboratory study.

4.1.7. Overview of mycotoxin testing

The audit team witnessed a demonstration of the bulk sample preparation procedures for mycotoxin testing, including the homogenisation of a rice sample and the preparation of a slurry sample of sultanas. In relation to the sultana sample, the analyst described the procedure to be followed for analysis of the sample. The Standard Operating Procedure (SOP PALC 0157 – the determination of type A and type B mycotoxins in food) was reviewed and found to contain a satisfactory level of detail to provide adequate instructions for staff to follow for the performance of official controls.

[3] 'The laboratory noted that, based on their experience, the methods referenced in the EFSA opinion are not yet widely used and their reliability across a range of matrices has not been examined.'

4.1.8. 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 of the FSAI service contract with the HSE regarding laboratory methods – 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 procedure SOP PALA 0001 Customer Enquiries, Service Level Agreements, Contracts and Contract Review details the method selection process, when it is not indicated by the customer. Section 3.5.10 details that: "When the customer does not specify the method to be used, select an appropriate method that has been published either in international, regional or national standards, or by reputable technical organisations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. Inform the customer of the method chosen."

4.1.9. 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. The validation files for Mycotoxin and PAH analyses were reviewed and the following documents were consulted:

1. SOP PALCS 0024F: The Validation of Test Methods Chemistry – Food
2. Validation Report - Analytical Method SOP PALC 0157 - The Determination of Type A and B Trichothecene Mycotoxins in Foodstuffs by UPLC-MS/MS - Trichothecenes in Cereals
3. SOP PALC 0157: The Determination of Type A and B Trichothecene Mycotoxins in Foodstuffs by UPLC-MS/MS
4. Validation Report for SOP PALC 0075: - Determination of PAH in Food

The reports provide validation for the major criteria listed in Annex III to Reg. 882/2004. In the case of the Validation Report for Trichothecene Mycotoxins, which is dated 31/01/2018, the report is structured according to SOP PALCS 0024F, dated 21/12/2015.

Certain criteria, such as Limit of Detection (LOD) and linearity, are not addressed in the Validation Report, although LOD and linearity values are given in SOP PALC 0157 (Table 6).

It is recommended that Validation Reports should clearly address all of the criteria listed in Annex III to Regulation (EC) No 882/2004.

4.1.10. Participation in external quality assurance and proficiency test schemes

Recital 17 of Regulation (EC) No 882/2004, requires that 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 Dublin PAL actively participates in External Quality Assurance (EQA) schemes and results were reviewed for a number of Proficiency Testing (PT) schemes undertaken by the laboratory, where the z-values were not within the assigned range (-2 and +2). In each case, where results were not within the assigned range, analysis of the cause was investigated as part of the laboratory's non-conforming work procedures. It was noted that the reasons assigned included errors in calculation and in chromatogram peak separation/integration. As part of the non-conforming work procedures, it was noted that no impact on test results were identified.

It is recommended that consideration continues to be given to any potential effect on future testing, where issues arise in proficiency testing.

Preventative action to address the issue of potential co-elution of cyclamate, an artificial sweetener, peak with matrix components has been identified and will be added to the relevant procedure by Dublin PAL. The audit team were satisfied with this preventative action.

4.1.11. Subcontracting of analysis methods

In accordance with section 4.4.7 of the FSAI service contract with the HSE regarding subcontracted testing. The Food Safety Laboratory Service may subcontract specific testing to another laboratory only if the subcontracted laboratory is, in so far as is possible, accredited to ISO/IEC 17025:2005 for that method, and in accordance with the Food Safety Laboratory Service documented procedures in their quality management systems for subcontracted testing. Responsibility for the Official control remains with the subcontracting laboratory. Results from subcontracted tests shall be reported through the LIMS extracts in line with the procedures agreed through the LIMS Administrators Working Group. The Authority shall be informed of such subcontracting.

Dublin PAL does not routinely subcontract any of its accredited tests. Section 4.5.1 of the quality manual details the laboratory approach and criteria for the use of subcontractors. This includes notification to customers of the fact that the testing is to be subcontracted as well as agreement regarding timelines and the subcontracted laboratory to be used (as appropriate). A register of approved subcontractors is maintained, and all subcontractors are authorised suppliers (in line with SOP PALA 10). There were three occasions in 2018 where Dublin PAL subcontracted testing which was relevant to this audit. One related to testing of a referee sample from an official control sample, where Dublin PAL had a non-compliant result. The other two cases related to requests to use a specific subcontracted

laboratory by the customer (FSAI). The timelines agreed in relation to reporting from subcontracted laboratories is inputted into the LIMS and monitored in the usual manner through the laboratory management team, should there be delays.

4.1.12. Reporting, designation and certification

In accordance with section 4.4.5 of the FSAI service contract with the HSE regarding reporting, designation and certification. The PALs shall implement the agreed procedures as outlined in 'Public Analysts' National Policy on Designation and Reporting of Analytical Results for Official Food samples'.

In accordance with section 1.15 regarding information systems, of the FSAI service contract with the HSE, the Official Agency Food Safety Laboratory Service shall share data on individual food samples taken under this contract, electronically to the Authority from the laboratory LIMS.

The Authority shall collate and analyse national data based on the data transmissions from the Food Safety Laboratory Service.

Electronic storage and transmission of results is described in SOP PALA 0014. This SOP details the automatic transmission of results to the FSAI by a File Transfer Protocol programme over the Government virtual private network. Dublin PAL are meeting the requirements in terms of data transmission. At the time of the audit, Dublin PAL indicted that they were taking part in an upgrade of the LIMS system, with a target for completion of Q1 2019.

Designation of results was not examined as part of the audit.

4.1.13. Staff performing official controls

Article 6 of Regulation (EC) No 882/20042004/220 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 1.23 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 following is an extract from section 5.2 of the laboratory's quality manual detailing the laboratory policy and approach to staff training:

5.2 Personnel

5.2.1 The laboratory management ensures the competence of all who operate specific equipment, perform tests, evaluate results, and sign test reports. When using staff who are undergoing training, appropriate supervision is provided. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

5.2.2 *The laboratory management formulate the goals with respect to the education, training and skills of the laboratory personnel.*

Policy
The Public Analyst's Laboratory recognises the importance of training and developing the potential of staff. All staff have received adequate training for the tasks and techniques which they are expected to perform. The Laboratory has a commitment to continuing in-house training and re-training, where necessary, of all staff.

Staff may attend external courses or workshops as deemed suitable by the Head of the Laboratory or the training may be conducted in-house. In-house training in analytical procedures is conducted by an experienced analyst, generally the Officer in Charge of the particular section in which the work is being carried out or a suitably trained staff member appointed by the Officer in Charge.
The training programme is relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken is evaluated.
The Public Analyst's Laboratory recognises the importance of re-training staff to perform infrequent Test Methods and has a training policy in operation.

Procedure: SOP PALA 0012
The trainer completes a report on the training programme undertaken by the trainee detailing the specifics of the programme he/she has designed on a Training Programme Report Form.

Assessments of training and competency are covered as part of the Quality Management System, and as part of the laboratory's accreditation to ISO 170125:2005, where it is also subject to assessment.

The audit team are satisfied that staff met during the audit were knowledgeable with regards to the official control testing being carried out.

4.1.14. Interaction / cooperation with National Reference Laboratories(NRLs)

In accordance with section 4.3 of the FSAI service contract with the HSE regarding official laboratories. 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 cooperate 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 NRL in the fulfilment of the NRL's role of coordinating the activities of official laboratories in their area of competence. Official laboratories for food are obliged under the service contract with FSAI to cooperate with the NRLs in the latters' discharge of their functions under Article 101 of Regulation (EU) 2017/625 on official controls and other official activities.

The Public Analyst's Laboratory, Dublin is both the official laboratory and national reference laboratory for PAHs, mycotoxins, plant toxins, and food contact materials and, as such, has all the information available to it for the necessary performance of both these functions. The Dublin PAL is both an official laboratory and national reference laboratory and sources the information necessary for the performance of its functions itself, from other National Reference Laboratories within the EU and also from the European Reference Laboratories (EURLs) for its areas of

competence. The laboratory participates in an annual programme of comparative testing, together with any additional comparative testing, organised by the EURLs for its areas of competence and maintains comprehensive records of these tests. It is a member of CEN TC275 WG5 for mycotoxins and plant toxins and participates actively in the development of new CEN analytical methods for these analytes by participating in interlaboratory trials. This is useful work, given the new requirements of Article 34 of Regulation (EU) 2017/625 on official controls and other official activities, regarding the selection of methods/hierarchy of methods to be used for official controls.

4.1.15. Duties of National Reference Laboratories

Article 33(2) of Regulation (EC) No. 882/2004 regarding National Reference Laboratories requires that:

These national reference laboratories shall:

a) collaborate with the Community reference laboratory in their area of competence;
b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11;
c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;
d) ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies;
e) provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53;
f) be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3), without prejudice to existing additional national duties.

The Dublin PAL participates in annual workshops organised by the EURLs for mycotoxins and plant toxins and for processing contaminants. The laboratory participates in (usually) two annual workshops organised by the EURL for FCMs. In recent years it has also participated in workshops dealing with the revision of the legislation on migration of lead and cadmium from ceramics (Reg. 84/500/EC) and also recent workshops on the drawing up of guidelines on and the implementation of analysis of mineral oils from food and FCMs. The laboratory also recently participated in a workshop on the new acrylamide regulation and in collaborative trials for monochloropropanediol (MCPD) and glycidyl esters.

Dublin PAL co-ordinates its own activities with respect to its areas of competence as it is both an official laboratory and national reference laboratory. There is some sharing of information regarding mycotoxins with the State Laboratory, which is the NRL for mycotoxins in feed.

The laboratory does not organise any comparative testing for other national official laboratories as it is the only official laboratory carrying out the testing of these parameters i.e. mycotoxins, FCMs etc. Because of the changing scope of the EURLs, the matter is kept under regular review. The PAL organises its own programme for comparative testing, participates in all the comparative testing organised by the EURLs within its areas of competence and carries out any appropriate follow-up where necessary. There have been three comparative testing programmes by the EURLs in 2018 – which related to FCMs, mycotoxins and process contaminants (including acrylamide).

Dublin PAL communicates frequently with the FSAI regarding its national reference laboratory role for PAHs, mycotoxins, plant toxins, and FCMs, through emails, and through reporting at joint FSAI/Laboratory meetings held

under the joint service level agreements between the FSAI and the Health Service Executive. Likewise, the laboratory receives regular information about the activities taking place at the legislative committees level of the European Commission with respect to new legislation, revision of existing legislation and other relevant activities.

Dublin PAL actively participates in the preparation of coordinated control plans on an annual basis through (i) developing analytical methods to meet the needs of the FSAI, (ii) participating in regular joint meetings between the FSAI and the laboratories, and (iii) participating in joint meetings between the FSAI, the laboratories and the Environmental Health Service(EHS) held under the service level agreements between the FSAI and the Health Service Executive.

4.1.16. 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 laboratory has a policy of maintaining a scope of accreditation and extending it wherever possible. Dublin PAL has a flexible scope which has been used to test and report on new matrices on an accredited basis. The laboratory continues to expand its scope of accreditation via the traditional approaches of extension applications at annual surveillance visits and also by correspondence.

Dublin PAL stated that it undertakes the following:

1. Constantly expands their scope of accreditation
2. Participates extensively and successfully in a wide variety of External Quality Assurance (EQA) Schemes
3. Actively promotes training to ensure staff receive both the in-house and external training that they require.
4. Cooperates with EURLs and with relevant NRLs
5. Participates in regular meetings with FSAI.
6. Participates in relevant FSAI committees
7. Liaises with the EHS
8. Liaises and cooperates with the two other PALs to deliver an effective service
9. Is subject to internal and external audits.

External audits are conducted by INAB as part of the laboratory's accreditation to ISO 17025:2005. The FSAI audit team reviewed a number of the non-compliances which had been identified during the last INAB audit. A systematic approach was applied for closing out these non-conformances.

Internal audits are carried out as part of the laboratory's accreditation to ISO 17025:2005. Vertical and horizontal audits are conducted as well as test witnessing (where a senior member of staff observes a staff member performing a test in order to assess competence). The audit reports and any associated non-compliances are managed through the LIMS. Responsibility for close out of non-compliances is monitored as part of the management team meetings and reports.

At the time of the audit, the next INAB audit against the requirements of the new version of the ISO 17025:2017 standard was scheduled for Quarter 1 2019.

4.2. Galway Public Analyst's Laboratory

4.2.1. Designation of official control laboratories

Article 4 of Regulation (EC) No. 882/2004 requires Member States to designate the competent authorities (CAs) 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.

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

The Public Analyst Laboratory (PAL) Galway, which, at the time of the audit was accredited to ISO 17025:2005, has been designated as an official laboratory for the performance of official controls in accordance with the requirements of Regulation (EC) No. 882/2004. The PAL operates as part of the Food Safety Laboratory Service (FSLS) within the FSAI Service Contract with the Health Service Executive (HSE).

The laboratory comprises of three sections; water, food and pharmaceutical. In relation to food, the laboratory's main official control activity involves the analysis of samples that have been taken by enforcement officers. These samples are taken to support inspections; as part of monitoring and surveillance programmes or as part of the investigation of an outbreak, incident, food alert or consumer complaint. There is a small amount of private testing for clients/the general public (78 samples in 2017 and 61 samples in 2018).

4.2.2. Organisational Structure of the Food Safety Laboratory Service within the HSE

Recital (16) of Regulation (EC) No 882/2004 requires that 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 4.2 of the FSAI service contract: National Management System for the Food Safety Laboratory Service

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. The Official Agency will review the existing management structures and implement an appropriate national structure for the Food Safety Laboratory Service during the term of the contract.

There is no national structure within the HSE, for coordination and management of the FSLS, which does not meet the requirements of section 4.2 of the HSE service contract with the FSAI (this finding is outstanding from a previous audit of the Official Food Microbiology Laboratories in 2014 by FSAI).

4.2.3. Operational criteria requirements

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

Article 4(2) requires that 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) requires that competent authorities shall ensure impartiality, consistency and quality of official controls at all levels.

Article 4(6) requires that 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 fulfil its obligations regarding food safety as agreed with the Authority under the terms of this contract.

Galway PAL informed FSAI, as part of the information returned in pre-audit questionnaire that the laboratory capacity for testing foods has decreased considerably over the past 7 or 8 years, due to:

- Decreased staff numbers due to non-replacement of staff in HSE (main factor)
- Staff Leave (maternity, parental, shorter working year etc.)
- The large increase in reporting demands including, inter alia:
  - additional parameters (performance characteristics – limit of quantification, uncertainty of measurement etc. – needed for EFSA data analysis) required for every analyte reported
  - additional data requested by FSAI for electronic reporting via LIMS
  - more complex interpretation and designations of results (due to need to designate results against legislative standards, but using non-legislative guides (EU nutritional labelling guidance document, European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) paediatricians' standards for infant formulae etc.)
  - More difficult designations of some sample categories, e.g. ELISA allergen results at low levels, food complaint samples.

Table 2: Overview of resources in Galway PAL

Grade /Title	All duties Total number of posts (Whole Time Equivalent (WTE))	All duties Total number of posts filled (WTE)	Food control Total number of staff	Food control Total number of posts filled (WTE)	Food control Total number of posts (WTE)
Administration Clerical Officer	5	3	5	2	2.5
Lab Senior Laboratory Technician	7	5	3	2	2
Lab Laboratory Technician	16.5	11	12	7.1	12
Lab Deputy Public Analyst	2	1	1	0.8	1
Lab Executive Analytical Chemist	10.5	9	8	6.3	8
Lab Public Analyst	1	1	1	0.5	0.5
Lab Quality Manager	1	1	0.5	0.5	0.5
Total	**43**	**31**	**30.5**	**19.2**	**26.5**

Staff training and competency is addressed in the quality management system (QMS) and as part of the accreditation to ISO 17025:2005 and is subject to internal and external audits.

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.

Galway PAL advised as part of the information returned in the pre-audit questionnaire that facilities and equipment were satisfactory, in general. Audits of "accommodation and environmental conditions" and "equipment" are carried out as part of the annual audit. Galway PAL noted that, it is essential however that there is continued investment in equipment, training, IT (including LIMS) to ensure instrumentation and procedures are kept up-to-date in order to comply with increasingly demanding testing and reporting 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.

Galway PAL operates a quality management system for all functions within the laboratory, which is accredited under ISO 17025:2005. In relation to management of potential staff conflict of interest, this is addressed in Quality Assurance Procedure:1: Conflict of Interest Policy.

4.2.4. Sampling and analysis

Arrangements are specified for the coordination of sampling and analysis between EHS and FSLS 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 EHS-PAL sampling groups in conjunction with the Authority. The official agency shall ensure national implementation of sampling and analysis decisions.

In accordance with clause 4.4.1 of the FSAI Service Contract, 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 Section 3 taking into account the relevant legislative requirements, guidelines and/or protocols.

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of chemical testing from central to regional level and local levels, as part of the national sampling programme. There were some deviations from the sampling programmes in 2016 and 2017, which related mainly to labelling examinations not being carried out on three HSE programmed surveys due to staff shortages.

Galway PAL reported no rejected samples in 2016, 2017 or 2018. The laboratory informed the audit team that there had been improvement in the packaging and transport of samples to the laboratory by the EHS. In Galway PAL, when a sample is received that is late for the allocated testing window, or should not have been sent to the laboratory, or Galway PAL does not conduct the testing requested, the laboratory communicates with the sampling officer and agrees appropriate action so that the sample taken is not rejected. This may include sending the sample to another PAL or suggestion of alternative testing that can be conducted at Galway PAL. In cases where samples are redirected to another PAL, they are not entered onto the LIMS, and so are not logged as rejected samples. Galway PAL noted that there is a very low incidence of such samples.

4.2.5. Documented procedures

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

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, requires that 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) of Regulation (EC) No 882/2004 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 examined laboratory procedures and records relating to:

- The laboratory's scope of accreditation
- The intake, handling and testing of samples
- The selection and validation of methods
- The assessment and on-going monitoring of method performance including participation in external proficiency testing schemes
- Internal and external audits
- Subcontracting of testing
- Procedures for control of non-conforming testing
- Service to the customer

Galway PAL had operational controls and procedures in place to verify the effectiveness of the official controls performed. The procedures reviewed were sufficiently detailed and comprehensive; and were regularly subject to audit (both internal and external) and review.

Non-conformances from audits are reviewed at management meetings as appropriate and a log is used to record issues that arise in relation to non-conforming work, these include details of cause analysis, the resolution (corrective/preventative action) and assessment of impact on results.

4.2.6. Laboratory scope of accreditation

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'

Section 4.4.2 of the Service Contract regarding accreditation requires that 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 requirements of Article 11 (2) and (3) of Regulation (EC) No. 882/2004. Over the duration of this contract, the Food Safety Laboratory Service will work toward expanding accreditation for all the methods used by the laboratories when testing Official control samples in the scope of this contract in so far as is possible.

The Official Agency will provide the Authority with up to date information on the scope of their accreditation.

Galway PAL was, at the time of the audit, accredited to ISO 17025:2005 and the laboratory advised that the next planned Irish National Accreditation Board (INAB) audit, in Quarter 4 2019 would be to assess the laboratory against

the requirements of the ISO 17025:2017 version of the standard. A transition plan had been developed, which included a gap analysis between the 2005 and the 2017 versions of the standard.

The current scope of accreditation for Galway PAL is listed on the INAB website: https://www.inab.ie/Directory-of-Accredited-Bodies/Laboratory-Accreditation/Testing/Public-Analyst-s-Laboratory-Galway.html. The published scope for Galway PAL, at the time of the on-site activity, was used as the basis for audit activities.

Galway PAL has been operating under flexible scope since 2009 and has used flexible scope to facilitate the extension of accredited tests by matrix and/or range of measurement. The use of flexible scope is covered in section K of their Quality Assurance Procedures manual.

The use of flexible scope was reviewed in relation to two tests:

- Sodium and potassium using atomic emission spectrophotometry (AES): extension to the matrix – processed vegetables; this was found to be satisfactory.
- Folic acid using liquid chromatography–mass spectrometry (LC-MS): extension to the matrix – dairy and oil spreads and food supplements; the validation information on file was satisfactory.

In relation to allergen testing, Galway PAL is accredited for gluten, peanut (ELISA kits) and sulphur dioxide (distillation method) for the matrices and range of measurement specified in the scope of accreditation. However, Galway PAL is not accredited for milk or egg allergens, and these two are listed in the 2019 sampling programme plan. Galway PAL indicated that it is their intention to extend the scope of accreditation to include testing of these allergens (ELISA kits), through the use of flexible scope.

In relation to sugars (glucose, fructose, sucrose), Galway PAL has indicated that validation of the method will be carried out in 2019 using an HSE programmed survey of soft drinks (survey of determined sugars levels versus labelled values, in the context of tax brackets for soft drinks).

Table 3: List of unaccredited test methods in Galway PAL

Analysis	Method on INAB Scope	Comments
Allergens – beta-lactoglobulin	No	To be accredited under flexible scope
Allergens - casein	No	To be accredited under flexible scope
Allergens - soy	No	To be accredited under flexible scope
Allergens - egg	No	To be accredited under flexible scope
Allergens - hazelnut	No	To be accredited under flexible scope
Allergens - almond	No	To be accredited under flexible scope

Analysis	Method on INAB Scope	Comments
Allergens – gliadin competitive	No	To be accredited under flexible scope
Minerals – calcium, manganese, iron, cobalt, zinc, copper, molybdenum, manganese	No	To be accredited under flexible scope
Ethanol	No	Drugs lab test
Folic acid USP	No	Being accredited at the time of the audit
Irradiation screening PPSL	No	New instrument purchased in 2018 and EN 13751 method used.
Labelling examination	No	Provision of an opinion
Mercury ICPMS	No	To be accredited under flexible scope

4.2.7. Overview of allergen testing

The audit team was provided with an overview of the allergen testing being carried out by Galway PAL which is accredited for the testing of three allergens in foods: gluten and peanut using the ELISA technique, and sulphur dioxide/sulphites using a distillation method.

In relation to the testing for sulphur dioxide/sulphites as an allergen, it was noted that the LOQ was set at 10 ppm; which is the legal limit above which sulphur dioxide / sulphites must be declared (in terms of the total SO_2) as set out in Regulation (EU) No 1169/2011 on the provision of food information to the consumer from an allergen labelling viewpoint. The audit team notes that an EFSA scientific opinion from 2016 on the re-evaluation of sulphur dioxide and sulphites notes improved sensitivity for a number of methods being employed to analyse sulphites.

Galway PAL indicated that the official testing for food allergens is a process in development, in response to the legislative requirement for the provision of allergen labelling information, which is in force since 2014. The service is of importance in the protection of consumers with food allergies. Testing is performed as part of the HSE annual food surveillance programmes which involves mainly programmed samples, but also food complaints (official and private). ELISA testing for gluten in 'gluten-free'[4] foods was introduced by Galway PAL in 1997.

The range of allergens tested for at the time of the audit included:

- Sulphur dioxide/sulphites

[4] The use of the 'gluten-free' declaration is voluntary and can only be used where the food as sold to the final consumer (either prepacked or non-prepacked) contains no more than 20 mg/kg of gluten.

- Gluten; hydrolysed gluten (for example, in gluten-free beers)
- Peanut
- Milk (casein and β-lactoglobulin).
- Egg
- Hazelnut, almond, soy.

The main programme surveys are for sulphur dioxide/sulphites, gluten, peanut, milk and egg allergens, with annual rotation of programmed testing for other allergens, e.g. hazelnut and soy as agreed with the EHS and the FSAI.

Test methods are as follows:

- Sulphur dioxide / sulphites - classical distillation/titration (testing for sulphites as allergen or additive)
- Other allergens – commercial ELISA Kit methods
- Tree nuts - some testing conducted by Galway PAL, but testing is often subcontracted to a commercial laboratory (ELISA and PCR tests).

Galway PAL outlined that the challenges in allergen testing include cross-reactivity/lack of specificity; a lack of certified reference materials; lack of legislative allergen limits for foodstuff (causing problems with results designation etc.); the wide food matrix range; sensitivity of testing and uncertainty of measurement. The laboratory as part of their work plans and service developments are looking at developing/adopting other methodologies such as LC-MS and liaising with the European Network of Food Allergen Detection Laboratories.

In preparation for the implementation of Regulation (EU) No. 2017/625 on official controls and other official activities, Galway PAL are working towards extended use of the flexible scope. Galway PAL will also work on informing decisions on surveys (parameters, food types etc.) in the 2020 HSE Surveillance Programme.

4.2.8. 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 of the FSAI service contract with the HSE regarding laboratory methods – 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.

Quality manual, section B4 is titled '*Test and calibration methods and method validation'* and details the method selection process, when it is not indicated by the customer.

Section B.4.2 of the Quality manual details that:

> *"The laboratory uses test methods that meet the needs of the customer and that are appropriate for the tests undertaken."*

- *In the Food section, the laboratory validated methods are contained in the relevant Methods Manuals.*

- *If the customer proposes a method considered by the laboratory to be inappropriate or out-of-date, the laboratory informs the customer of this.*

4.2.9. 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. The validation files for (i) folic acid by LC-MS in food supplements and in dairy and oil spreads (extension to matrices) and (ii) volatile organic compounds in water were reviewed and all parameters had been satisfactorily validated.

The validation reports provide validation for the major criteria listed in Annex III to Regulation (EC) No. 882/2004.

4.2.10. Participation in External Quality Assurance (EQA) - Proficiency Test (PT) schemes

Recital 17 of Regulation (EC) No 882/2004, requires that 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 laboratory actively participates in External Quality Assurance (EQA) schemes. The EQA schemes designate a z-score of between -2 and +2 as satisfactory, results between |2| and |3| as questionable and results greater than +3 or less than -3 as unsatisfactory. The audit team reviewed EQA results where the z-values were above +2 or below -2. As part of the management of proficiency tests, Galway PAL keeps a record of the proficiency test results and so can identify any trends. For 2017 and 2018, approximately 1.5% of z-scores were designated as "unsatisfactory" and 2.7% as "questionable".

Two Fapas proficiency tests for selenium in infant formulae carried out in 2017 and 2018 were reported by the laboratory at <200 µg/kg, which corresponds to the LOQ (assigned values were 171 and 149 µg/kg, respectively). This method does not allow for testing of samples at the legislative limits of 1-3 µg/100 kcal (SI 187/2009) (the conversion between measurement units is determined based on the product's labelled energy value [kcal/100 g]). It is recommended that the laboratory should consider lowering the LOQ for the selenium method to satisfy the legal requirements.

In relation to the Fapas proficiency test for zinc in breakfast cereal in January 2017, it was noted that there had been a miscalculation with the blank value which resulted in a non-conforming z-score (z-score = +21.5). This led to the development of a non-conforming report, "NCR food 3-17", which included cause analysis and corrective action. However, it was noted that this non-conformance was closed out on 31st October 2018.

The results of Fapas proficiency testing in 2017 and 2018 for sulphur dioxide in meat were examined by the audit team. The 2017 result was non-conforming (z-score = -4.2) and was followed up with an investigation but no cause was identified. A repeat analysis for this sample was satisfactory. In relation to the 2018 proficiency test for sulphur dioxide in meat, a questionable result (z score = -2.1) was attained. There was discussion with the audit team regarding the need for a correction factor because of a trend of under-estimation of sulphur dioxide in meat.

The results of Aquacheck proficiency tests for sulphate in water were reviewed and a trend of over-estimation was observed for samples with low assigned values (<20 mg/L) (also less than the LOQ for the method). Galway PAL suggested that use of a separate standard curve for low content samples might be beneficial.

4.2.11. Subcontracting of analysis methods

In accordance with section 4.4.7 of the FSAI service contract with the HSE regarding subcontracted testing. The Food Safety Laboratory Service may subcontract specific testing to another laboratory only if the subcontracted laboratory is, in so far as is possible, accredited to ISO/IEC 17025:2005 for that method, and in accordance with the Food Safety Laboratory Service documented procedures in their quality management systems for subcontracted testing. Responsibility for the Official Control remains with the subcontracting laboratory. Results from subcontracted tests shall be reported through the LIMS extracts in line with the procedures agreed through the LIMS Administrators Working Group. The Authority shall be informed of such subcontracting.

Galway PAL does not routinely subcontract any of its accredited tests. Section A5 of the quality manual details the laboratory approach and criteria for use of subcontractors. This includes notification to customers of the fact that the testing is to be sub-contacted as well as agreement with regards to the subcontracted laboratory to be used. At Galway PAL, subcontracting is agreed on a case by case basis, with approval being given by the relevant technical manager. Records of any subcontracted testing are maintained in a spreadsheet. There were 4 occasions in the past year where Galway PAL subcontracted testing, which is relevant to this audit.

The reasons testing may be subcontracted include:

- Galway PAL does not have an accredited test (e.g. marine biotoxins are subcontracted to the Marine Institute)
- Due to difficulties with the analysis of the matrix (e.g. spirulina algae for sulphur dioxide)
- Complaint samples requiring full tree nut analysis (e.g. almond, hazelnut, walnut, cashew, pecan, Brazil nut, pistachio and macadamia/Queensland nut).

In certain cases, allergen testing at another laboratory is used to provide a second opinion in relation to results that are near to the LOQ.

4.2.12. Reporting, designation and certification

In accordance with section 4.4.5 of the FSAI service contract with the HSE regarding reporting, designation and certification. The PALs shall implement the agreed procedures as outlined in 'Public Analysts' National Policy on Designation and Reporting of Analytical Results for Official Food samples'.

In accordance with section 1.15 regarding information systems, of the FSAI service contract with the HSE. The Official Agency Food Safety Laboratory Service shall share data on individual food samples taken under this contract, electronically to the Authority from the laboratory LIMS.

The Authority shall collate and analyse national data based on the data transmissions from the Food Safety Laboratory Service.

Reporting of test results is described as an SOP in the Quality Manual Section B 10. To-date in 2018, there have been 39 extract reports, which related to over 1,200 samples. There is also regular (normally weekly) transfer of sample results through the LIMS to the FSAI.

At the time of the audit, Galway PAL indicated that they were taking part in an upgrade of the LIMS, with an expected completion date of May 2019.

A discussion regarding the interpretation of results and inclusion of the approved examiner's opinion in the certificates of analysis was held.

An error was noted in respect of a certificate of analysis for sodium in dietary food for special medical purposes issued in April 2018. Galway PAL has committed to undertake corrective actions (such as issuing an amended certificate of analysis, communication with the sampling officer, re-sampling and testing). During the FSAI audit, Galway PAL conducted a cause analysis which included assessment of impact on results issued for similar tests and advised that there was no further impact on results issued, outside of this incident. This audit finding was categorised as a non-compliance and has been included in the corrective action plan.

4.2.13. Staff performing official controls

Article 6 of Regulation (EC) No 882/20042004/220 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 1.23 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.

Assessments of training and competency are covered as part of the QMS, and as part of the laboratory's accreditation to ISO 170125:2005. Competency is subject to both internal and external audit, as well as test assessments, as part of staff training. The audit team's view is that staff met during the course of the audit were knowledgeable with regards to the official control testing being carried out.

4.2.14. Interaction/cooperation with National Reference Laboratories (NRLs)

In accordance with section 4.3 of the FSAI service contract with the HSE regarding official laboratories. 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 cooperate 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.

Galway PAL provides information to Cork PAL (as the NRL for heavy metals) as requested; this information is submitted on an annual basis as a minimum.

4.2.15. Duties of National Reference Laboratories (NRLs)

Article 33(2) of Regulation (EC) No. 882/2004 regarding National Reference Laboratories requires that:

These national reference laboratories shall:

a) collaborate with the Community reference laboratory in their area of competence;
b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11;
c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;
d) ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies;
e) provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53;
f) be responsible for carrying out other specific duties provided for, in accordance with the procedure referred to in Article 62(3), without prejudice to existing additional national duties.

Galway PAL has no NRL functions.

4.2.16. 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.

Internal audits are carried out as part of the laboratory's accreditation to ISO 17025:2005. Vertical and horizontal audits are conducted as well as method assessments. The audit reports and any associated non-compliances were well documented.

The next INAB audit against the requirements of the ISO 17025:2017 version was scheduled for Quarter 4 2019. A transition plan has been developed. The results of the last INAB audit were reviewed and the corrective actions regarding a number of minor non-conformances were found to be satisfactory.

4.3. Cork Public Analyst's Laboratory

4.3.1. Designation of official control laboratories

Article 4 of Regulation (EC) No. 882/2004 requires Member States to designate the competent authorities (CAs) 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:

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

Cork Public Analyst Laboratory, which is accredited to ISO 17025:2005, has been designated as an official laboratory for the performance of official controls in accordance with the requirements of Regulation (EC) No 882/2004. The PAL carries out food control testing (chemical testing) as part of the FSLS and is included in the FSAI Service Contract with the Health Service Executive.

The laboratory's main activities involve the analysis of samples that have been taken by food safety inspectors (EHS, SFPA, DAFM, LAs) during their visits to food business operators. These samples are taken to support inspections, 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 in relation to food complaints, quality control verification and the export of food.

4.3.2. Organisational structure of the Food Safety Laboratory Service (PALs) within the HSE

Recital (16) of Reg 882/2004 requires that 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 4.2 of the FSAI service contract: National Management System for the Food Safety Laboratory Service

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. The Official Agency will review the existing management structures and implement an appropriate national structure for the Food Safety Laboratory Service during the term of the contract.

There is no national structure within the HSE, for co-ordination and management of the FSLS, which does not meet the requirements of section 4.2 of the HSE service contract with the FSAI (this finding is outstanding from a previous audit of the Official Food Microbiology Laboratories in 2014 by FSAI).

4.3.3. Operational criteria requirements

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

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 fulfil its obligations regarding food safety as agreed with the Authority under the terms of this contract.

Cork PAL reported as part of the information returned to FSAI in the pre-audit questionnaire that the laboratory has adequate staffing levels (Laboratory Technicians and Executive Analytical Chemists) to ensure efficient and effective food testing. However, the post of Deputy Public Analyst has not been filled since 2004 because of an embargo on recruitment in the HSE since 2003. This has added to the work load of the Public Analyst who advised the audit team that the post of deputy PA has subsequently been lost. At the time of the audit the recruitment for the replacement of a Senior Laboratory Technician Posts was being processed by the HSE-HR Dept.

Table 4: Overview of resources in Cork Public Analyst's Laboratory

Grade /Title	All duties Total number of posts (Whole Time Equivalent (WTE))	All duties Total number of posts filled (WTE)	Food control Total (number of staff)	Food control Total number of posts filled (WTE)	Food control Total number of posts (WTE)
Clerical Officer	2	1.2	2	0.85	2
Executive Analytical Chemist	10	8.0	9	7.2	9
Laboratory Technician	9	8.6	6	5.6	6
Senior Laboratory Technician	3	2.7	2.7	2.7	2.7
Deputy Public Analyst	1	0	0	0	0
Public Analyst	1	1	0.75	0.75	0.75
Total	**26**	**21.5**	**20.45**	**17.1**	**20.45**

Staff training and competency is addressed in the quality management system (QMS) and as part of the accreditation to ISO 17025:2005 and is subject to internal and external audits.

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.

Cork PAL informed the audit team that:

The laboratory has a wide range of analytical equipment. This includes:

Table 5: Overview of analytical equipment in Cork Public Analyst's Laboratory

Equipment	Number
High Performance Liquid Chromatography (HPLC) systems	8

Equipment	Number
Gas Chromatographs	3
Inductively Coupled Plasma Mass Spectrometry (ICP-MS) systems	2
Liquid Chromatography Mass Spectrometry (LC-MS)/MS system	1
Atomic Absorption Spectrophotometer (AAS)	1
Steam Distillation Units	2
Microwave Digestion Systems	2

Table 6: Overview of analytical balances in Cork Public Analyst's Laboratory

Analytical Balances	Number
DNA Identification systems	2
Density Meter	1

There are maintenance contracts on all the equipment. However, several of the High Performance Liquid Chromatography (HPLC) systems are more than 10 years old and in the opinion of management need to be replaced. It is envisaged that the replacement of the HPLC systems will take place on a phased basis. One new HPLC for colour analysis was commissioned in the weeks before the audit.

The audit team were informed that the procurement of a new GC-MS System for analysis of pesticides in bottled waters was underway at the time of the audit. A new LC-MS/MS System is required for the analysis of illegal dyes, such as the Sudan dyes in foods, in order to satisfactorily detect these dyes at trace/low levels and to reduce the LOQs of the current methodology (i.e. <10 µg/kg).

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.

Cork PAL operates a quality management system for all functions within the laboratory, which is accredited to ISO 17025:2005. In relation to management of potential staff conflict of interest, this is documented in the Laboratory Management Manual, as well as in the HSE Code of Standards and Behaviour. Cork PAL indicated that staff are not

subject to pressure or inducement that might adversely influence their judgement or the quality of their work. The laboratory does not engage in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity.

4.3.4. Sampling and analysis

Arrangements are specified for the coordination of sampling and analysis between EHS and FSLS 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 EHS-PAL sampling groups in conjunction with the Authority. The official agency shall ensure national implementation of sampling and analysis decisions.

In accordance with clause 4.4.1 of the FSAI Service Contract, 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 Section 3 taking into account the relevant legislative requirements, guidelines and/or protocols.

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of chemical testing from central to regional level and local levels, as part of the national sampling programme. There was a deviation from the sampling programme in 2016, which related to authenticity testing of basmati rice samples, which had not been included in the sampling programme.

Cork PAL reported no rejected samples in 2016 or for 2018 up to the end of September. There were two incidences of rejected samples in 2017. One set of samples (lettuce) were not fit for analysis due to decomposition. The other incident related to three meat samples submitted together and the sample size in each case was insufficient for the required analysis. Communications with the sampling officer were reviewed in relation to the lettuce samples, and detailed records had been maintained of these. In both incidences the sampling officer was offered the opportunity to re-submit fresh samples for analysis.

4.3.5. Documented procedures

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

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, requires that 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) of Regulation (EC) No 882/2004 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.

Cork PAL operates a quality management system, accredited, at the time of the audit, to ISO 17025:2005. The audit team reviewed laboratory procedures and records relating to:

- The laboratory's scope of accreditation,
- The intake, handling and testing of samples,
- The selection and validation of methods,
- The assessment and on-going monitoring of method performance including participation in external proficiency testing schemes,
- Internal and external audits,
- Subcontracting of testing,
- Procedures for control of non-conforming testing and
- Review of requests, tenders and contracts.

Cork PAL had operational controls and procedures in place to verify the effectiveness of the official controls performed. The procedures reviewed were sufficiently detailed and comprehensive; and were subject to annual audit (both internal and external) and review.

Non-conformances from audits are tracked as part of the audit process and are logged on the audit summary sheet. The root cause analysis of the non-conformance is assessed by the public analyst and this includes assessment of the impact on results. This assessment includes looking at preventative action(s) in order to address any potential issues that may arise in the future in relation to the findings. Close out of non-conformances is tracked on the audit forward plan. The non-conformances are also discussed at the Quality Management System management review meetings, held in April and September.

Non-conforming test results are recorded on a non-conforming test results form and completed with an associated corrective action. An example was reviewed where there had been low recovery of Vitamin C. The root cause analysis identified that two batches were affected, and the corrective action was to review the recovery limits as well as the purchase of a new standard. Implementation of the corrective action was on-going at the time of the audit.

4.3.6. Laboratory scope of accreditation

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'.

Section 4.4.2 of the Service Contract regarding accreditation requires that 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 requirements of Article 11 (2) and (3) of Regulation (EC) No. 882/2004. Over the duration of this contract, the Food Safety Laboratory Service will work toward expanding accreditation for all the methods used by the laboratories when testing official control samples in the scope of this contract in so far as is possible.

The Official Agency will provide the Authority with up to date information on the scope of their accreditation.

Cork PAL was, at the time of the audit, accredited to ISO 17025:2005 and advised that the next planned INAB audit was scheduled for Q2 2019 would be to the ISO 17025:2005 version of the standard. A gap analysis between the 2005 and the 2017 standard had commenced, and it was planned that staff would attend training on the 2017 standard in early 2019.

The current scope of accreditation for Cork PAL is listed on the INAB website: https://www.inab.ie/Directory-of-Accredited-Bodies/Laboratory-Accreditation/Testing/Public-Analyst-s-Laboratory-Cork.html. The published scope for Cork PAL, at the time of the on-site activity, was used as the basis for audit activities.

Cork PAL does not have flexible scope but extend their accreditation each year by INAB audit. These extensions relate to extensions of the scope of existing methods as well as the validation of new methods.

The entry for sodium nitrate and sodium nitrite on page 6 of the INAB schedule of accreditation (24.10.2018) for Cork PAL should be confined to brines only and the range needs to be corrected (i.e. 60-2000 mg/kg).

Cork PAL specialises in the following areas: Metals (As, Cd, Hg, Pb, Al, Ni) in all foods, meat speciation, fish speciation, GMOs, vitamins in infant formulae, milk, food supplements, permitted artificial colours, illegal colours in foods, monosodium glutamate in snack foods, oriental foods etc., propionic acid in foods, 4-hexylresorcinol in prawns, congeners in spirits, nucleotides in infant formulae, compositional analyses of meat products (ash, water content, protein, total fat, hydroxyproline, collagen content).

There were a number of non-accredited test methods that were in the process of validation, at the time of the audit. Comprehensive audits of these methods and the status of the validation work had been undertaken. Reports on each non-accredited test method audit had been developed and these included clear detail in relation to validation work outstanding in each case.

Table 7: Validation status of non-accredited test methods

Method No.	Method and Parameters	Status
1/18	Sugar and Total Dissolved Solids in jam, marmalades, preserves and chutneys by Abbe Refractometer	Validation to be carried out in 2019
1/41	Fish speciation by PCR	Awaiting publication of CEN method to facilitate validation
2/9	Pesticides in water by GC-ECD	Validation to be carried out in 2020
2/15	Omega-3 (ALA) in butter spreads by GCFID	Low number of samples, validation of method to be discussed with FSAI
2/16	Omega-6 (ALA) in butter spreads by GCFID	
3/9	Vitamin A in food supplements by HPLC	Validation to be continued in 2019, but may not be complete until 2020
3/24	Biogenic Amines in fish and cheese by HPLC	Validation to be carried out in 2019
3/28	Vitamin B1 in infant formulae and food supplements by HPLC	Validation to be continued in 2019, but may not be complete until 2020
3/32	Illegal Dyes (Sudan Red etc.) in chillies, chilli powder, chilli sauce and palm oil by LC-MS/MS	Will continue to be subcontracted
3/41	Vitamin D in infant formulae by LC-MS	Validation to be continued in 2019, but may not be complete until 2020
4/8	Aluminium in food by ICP-MS	Validation to be continued in 2019, but may not be complete until 2020
4/22	Iodine in infant formulae by ICP-MS	Validation to be carried out in 2019

4.3.7. Overview of heavy metal testing

The audit team were provided with an overview of the heavy metal testing being carried out by Cork PAL and noted that in general, there were documented and detailed procedures for heavy metal analysis. These procedures were included in the Laboratory Management Manual, Section 21: Handling of test items as well as in the specific methods for analysis of samples for heavy metals. Reporting of results was described in section 23 of the Laboratory Management Manual.

It was observed that the ranges set for the method for some of the heavy metals were overly restrictive (cadmium and mercury). In the case of cadmium, the LOQ is at or above the maximum permitted level for some matrices, particularly infant formulae and follow on formulae, as laid down in Regulation (EC) 1881/2006. For mercury it was observed that the upper limit of the method is below the maximum levels set for this analyte in all matrices listed in Regulation (EC) 1881/2006.

Cork PAL should consider approaches to dealing with this problem through using different sample sizes, dilution of samples, etc. The laboratory should consider lowering the LOQ for the cadmium method to satisfy the legal requirements of Regulation (EC) No. 1881/2006. The laboratory should address the issue that non-compliant results above the upper limit of the method for mercury are currently reported as unaccredited, which is unsatisfactory. This audit finding was categorised as a non-compliance and has been included in the corrective action plan.

4.3.8. 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 of the FSAI service contract with the HSE regarding laboratory methods – 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.

Section 18 of the Laboratory Management Manual states that:

"The test methods and method validation section details the method selection process, when it is not indicated by the customer. Standard reference methods are used where available. However, in-house developed methods are also used which have been published by reputable technical organisations, relevant scientific journals or as specified by manufactures/suppliers of analytical instruments."

In relation to the testing for sulphur dioxide and sulphites as an additive, it was noted that the LOQ was set at 10 ppm; which is the legal limit above which sulphur dioxide and sulphites must be declared (in terms of total SO_2) from an additive as well as from an allergen labelling viewpoint. The audit team notes that an EFSA scientific opinion from 2016 on the re-evaluation of sulphur dioxide and the sulphites notes improved sensitivity for a number of methods being employed to analyse sulphites.

4.3.9. 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. The validation files for the following four methods were reviewed:

1. **Artificial colours in foods**
   The validation method report for this method was satisfactory. There was discussion regarding the need for sample recovery correction for certain matrices, where low recovery was found.

2. **GMOs in maize products – Nk603 maize, Go21 maize, Mon 863 maize, Bt-11 maize, Bt-176 maize events**

3. **Meat speciation in meat and meat products – beef, chicken and pork meat species.**
   The validation reports for these two methods were satisfactory. As part of the review of the validation information on meat speciation, FAPAS 2977 on meat authenticity was also reviewed and found to be satisfactory.

4. **Aluminium, arsenic, cadmium, chromium, lead, nickel and selenium in waters (including bottled waters) by ICP-MS.**
   The validation report for this method was comprehensive and satisfactory.

The validation reports provide validation for the major criteria listed in Annex III to Regulation (EC) No 882/2004.

4.3.10. Participation in External Quality Assurance (EQA) - Proficiency Test (PT) schemes

Recital 17 of Regulation (EC) No 882/2004, requires that 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 laboratory actively participates in external quality assurance schemes and results were reviewed for a number of proficiency tests undertaken by the laboratory; where the z-values were greater than +2 and lower than - 2, or where z-scores had not been issued.

1. Proficiency testing for arsenic, cadmium, lead and mercury in canned crab meat in 2018 were reported by the laboratory as follows:

Table 8: Proficiency testing in canned crab meat

Metal	Result	z-score
Arsenic	> 4.0 mg/kg	No z-score issued
Cadmium	> 4.0 mg/kg	No z-score issued
Lead	--	-2.01
Mercury	--	0.7

An appropriate investigation was undertaken for the low z-score recorded for lead. The issue with arsenic and cadmium is unclear; dilution for over-range samples would appear appropriate and is included in section 6.8 of the method SOP (4/9).

2. Proficiency testing for iodine, aluminium and cadmium in infant formulae were reported as follows:

Table 9: Proficiency testing in infant formulae

Metal	Result	z-score
Iodine	--	0.6
Aluminium	< LOQ	No z-score issued
Cadmium	--	0.6

Aluminium is not an accredited test and work is on-going on method development, which may include the possibility of achieving a lower LOQ.

3. During the assessment of the proficiency testing conducted in relation to nitrate in cabbage, the z-score was reported as -3.0. There was a detailed investigation of this non-conformance and the possible cause was identified and a corrective action has been implemented to rectify it. The performance of the method will be assessed with subsequent proficiency testing, which is planned. No customer samples were affected, as the Cork PAL was not testing for nitrates in vegetables, at the time of the audit.

4. Proficiency testing for maize and soya GM events in baked products were reported as follows:

Table 10: Proficiency testing in baked goods

GM Event	Result	Outcome
GA21 Maize	Not detected	Agreed with the consensus
NK603 Maize	Not Detected	Agreed with the consensus
MON 863 Maize	Detected	Satisfactory
Bt 176 Maize	Not Detected	Agreed with the consensus
Bt11 Maize	Not Detected	Agreed with the consensus
MON 1810 Maize	Detected	Satisfactory

GM Event	Result	Outcome
P35s (promoter)	Detected	Satisfactory
Tnos (terminator)	Detected	Satisfactory
RR (40-3-2) Soya	Not Detected	Consensus 76% Detected (positive), expected result not known. The performance of the laboratory was satisfactory.

5. Proficiency testing for aluminium, antimony, arsenic, barium, boron, cadmium, lead, mercury, nickel and selenium in water were reviewed. Results for a number of parameters (aluminium – z-score 1.99, antimony – z-score 2.07, barium – z-score 2.40) related to a proficiency test were assessed. Barium and antimony were investigated, and no cause was determined. A further, subsequent proficiency test was within specification. No customer samples were affected. A trend analysis is carried out each year to assess the performance in the "Aquacheck" and EPA proficiency testing schemes (5 samples per year each).

4.3.11. Subcontracting of analysis methods

In accordance with section 4.4.7 of the FSAI service contract with the HSE regarding subcontracted testing. The Food Safety Laboratory Service may subcontract specific testing to another laboratory only if the subcontracted laboratory is, in so far as is possible, accredited to ISO/IEC 17025:2005 for that method, and in accordance with the Food Safety Laboratory Service documented procedures in their quality management systems for subcontracted testing. Responsibility for the Official control remains with the subcontracting laboratory. Results from subcontracted tests shall be reported through the LIMS extracts in line with the procedures agreed through the LIMS Administrators Working Group. The Authority shall be informed of such subcontracting.

The Cork PAL policy on subcontracting is documented in Section 5 of the Laboratory Management Manual. Subcontracting of testing is assessed on a case-by-case basis only. Routine testing is not subcontracted, unless for reasons of equipment breakdown. It is a requirement of the documented procedures that subcontracted work shall be placed with a competent subcontractor. Where possible, the work shall be given to a subcontractor which has ISO 17025:2005 accreditation for the subcontracted tests. This includes notification to customers in writing of the fact that the testing is to be sub-contacted as well as gaining approval to subcontract, where appropriate.

There were nine occasions in 2017 and 2018 where Cork PAL subcontracted testing which was relevant to this audit. Testing may be subcontracted if Cork PAL does not have an accredited test. For example, meat speciation testing (DNA method) prior to accreditation in May 2018, olive oil analysis (chemical and organoleptic testing), vitamin D3 (in breakfast cereals, cheese strings, food supplement for babies and yoghurt), vitamin B6 analysis (in food supplements), illegal dyes (in chilli sauces and palm oils), GMOs (in soya flour) and fish speciation.

4.3.12. Reporting, designation and certification

In accordance with section 4.4.5 of the FSAI service contract with the HSE regarding reporting, designation and certification, the PALs shall implement the agreed procedures as outlined in 'Public Analysts' National Policy on Designation and Reporting of Analytical Results for Official Food samples.

In accordance with section 1.15 regarding information systems, of the FSAI service contract with the HSE, the Official Agency Food Safety Laboratory Service shall share data on individual food samples taken under this contract, electronically to the Authority from the laboratory LIMS.

The Authority shall collate and analyse national data based on the data transmissions from the Food Safety Laboratory Service.

Reporting of results is detailed in Section 23 of the Laboratory Management Manual. There is a six-week turnaround time from sample receipt. Any sample reports that are outside this range are flagged on the LIMS and overdue sample results are managed by the analyst responsible for the area of testing. When sample results are outside the six-week turnaround time, the sampling officer is contacted to advise of the delay.

Between January and the end of September 2018, there had been 41 extract batches of results reported, which related to over 1,426 samples.

At the time of the audit, Cork PAL indicated that they were taking part in an upgrade of the LIMs system, and pilot testing of the upgraded system was scheduled for the end of January 2019.

Designation of results was not examined as part of the audit.

4.3.13. 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 1.23 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.

Assessments of training and competency are covered as part of the QMS, and as part of the laboratory's accreditation to ISO 170125:2005, where it is subject to both annual internal audit and external INAB audit as well as vertical audits. There is a training competence review conducted for each analyst on an annual basis, which is completed by the Public Analyst or the Quality Manager. The audit team's view is that staff met during the course of the audit were knowledgeable with regards to the official control testing being carried out.

4.3.14. Interaction / cooperation with National Reference Laboratories(NRLs)

In accordance with section 4.3 (Official Laboratories), of the FSAI service contract with the HSE - The FSLS shall function as 'official laboratories' as defined in Regulation (EC) In accordance with section 4.3 of the FSAI service contract with the HSE regarding official laboratories. 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 cooperate 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.

Cork PAL is an NRL for heavy metals in food; specifically, arsenic, cadmium, mercury and lead in food of non-animal origin and wild caught fish. Cork PAL does not do any of the work for which Dublin PAL is a national reference laboratory (mycotoxins and PAHs in foods and food contact materials).

4.3.15. Duties of National Reference Laboratories(NRLs)

Article 33(2) of Regulation (EC) No. 882/2004 regarding National Reference Laboratories requires that:

These national reference laboratories shall:

a) collaborate with the Community reference laboratory in their area of competence;
b) coordinate, for their area of competence, the activities of official laboratories responsible for the analysis of samples in accordance with Article 11;
c) where appropriate, organise comparative tests between the official national laboratories and ensure an appropriate follow-up of such comparative testing;
d) ensure the dissemination to the competent authority and official national laboratories of information that the Community reference laboratory supplies;
e) provide scientific and technical assistance to the competent authority for the implementation of coordinated control plans adopted in accordance with Article 53;
f) be responsible for carrying out other specific duties provided for in accordance with the procedure referred to in Article 62(3), without prejudice to existing additional national duties.

Cork PAL is the National Reference Laboratory for heavy metals in food of non-animal origin and wild caught fish.

Cork PAL collaborates with the European Union Reference Laboratory (EURL) for heavy metals by participating in annual workshops and proficiency testing schemes organised by the EURL as well as disseminating any information available from the EURL regarding heavy metals.

Cork PAL collaborates with Galway PAL, Dublin PAL, FSAI, and the EHS in relation to sampling and foods taken as official food control samples, for metal analyses, as agreed in the annual food sampling and analysis programmes. The laboratory also accepts samples from DAFM (vegetables) and the SFPA (fish) for metal analyses as part of the annual food sampling and analysis programme.

The organisation of comparative tests among Official Food Control Laboratories (i.e. Galway and Dublin PALs) is not necessary as they participate in the UK Food and Environment Research Agency (FERA) proficiency testing schemes.

Cork PAL issues the reports on the annual EURL heavy metal workshops to both Dublin and Galway PALs. They contain information on a wide range of topics such as method development, quality control requirements, new parameters, new analytical methods etc.

Scientific and technical assistance has been provided to the FSAI in relation to inclusion of heavy metals testing in the annual food sampling and analysis programmes and inclusion of new parameters (e.g. nickel) and food matrices in the programmes.

In May 2018, the EURL for heavy metals moved from the Institute for Reference Materials and Measurements (IRMM), Geel, Belgium to the University of Copenhagen and is known as the EURL for Heavy Metals and Nitrogenous Compounds (residues). The 1st Annual Meeting/Workshop was held in Copenhagen on the 14th and 15th November 2018.

4.3.16. 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.

An extensive programme of internal audits is carried out as part of the laboratory's accreditation to ISO 17025:2005. Vertical and horizontal audits are conducted as documented in the annual audit forward planner. Method observations are conducted on a five-year plan, the aim of which is to review each method within the five-year cycle. The quality manager advised that method observations are being conducted at a greater frequency than the programmed five-year cycle. The audit reports and any associated non-compliances reviewed by the audit team were documented in a comprehensive manner.

The results of the last INAB audit were reviewed as was the implementation of corrective actions regarding a number of minor non-conformances. Following on from the INAB audit, Cork PAL has introduced a new change control process, which is included as part of the continuous improvement process. This change control process will be used to manage changes within the PAL, such as equipment upgrade, etc. It has been utilised to manage the change control process associated with the upgrading of the HPLC and the LIMS upgrade. The process is generic, but well documented and includes the assessment of training requirements, changes to procedures, safety assessments, documentation of the change implementation plan as well as monitoring of the proposed changes.

5. Overall Audit Conclusions and Recommendations

5.1. Audit conclusions

A structured approach to the delivery of official control testing under the requirements of the service contract was noted in each of the three PALs. The maintenance of the accreditation to ISO 17025:2005, participation in external quality assurance schemes as well as internal and external audits contributed to the effective performance of official controls. At the time of the audit, each of the three laboratories had commenced preparations for assessment by INAB of compliance with the requirements of ISO 17025:2017 and Regulation (EU) 2017/625 on official controls and other official activities.

Flexible scope was in use in two out of the three laboratories. The effective use of the laboratory management process as a management tool in the Dublin PAL was identified as a strength by the audit team. Differences were observed in the manner in which rejected samples are logged in the laboratories and this may need to be reviewed in order to improve consistency across the service. The absence of a national structure within the HSE, for co-ordination and management of the FSLS, hampers consistency and progression within the Public Analyst Laboratory service at a national level. The implementation of a national structure is a requirement of the FSAI - HSE service contract and had also been identified as not being in place during a previous FSAI audit of the Official Food Microbiology Laboratories; yet remains outstanding.

5.2. Audit recommendations

In addition to the non-compliances identified during the audit, and detailed as part of the corrective action plan, a number of recommendations are made to address additional opportunities for improvement.

- Some incidences were noted where the test methods being used by the laboratories were not sufficiently sensitive to allow for testing at the legal limit for the test parameter, that is, the LOQs for the tests used were above legal limits set for the test parameter. It is recommended that consideration should be given to lowering the LOQ to satisfy the legal requirements in such cases.
- At the time of the audit, an error was noted in relation to the entry on the schedule of accreditation listed on the INAB website for one PAL. It is recommended that the published accreditation should be monitored more closely, and corrections notified to INAB to ensure accuracy is maintained.
- It is recommended that Validation Reports should clearly address all of the criteria listed in Annex III to Regulation (EC) No 882/2004.
- It is recommended that, where issues arise in proficiency testing, consideration should be given to any potential effect on future testing.

6. Audit Findings Requiring Corrective Action

Audit findings requiring corrective action are listed in the corrective action plan. The corrective action plan can be accessed here.

Food Safety Authority of Ireland
The Exchange, George's Dock, IFSC,
Dublin 1, D01 P2V6

T +353 1 817 1300
E info@fsai.ie


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