

AUDIT
REPORT

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

CORRECTIVE ACTION PLAN

NOVEMBER 2015



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This corrective action plan describes audit findings requiring corrective action, documents responsibility for addressing the findings and describes progress on the close-out of actions.

Audit: Audit of Compliance of Official Food Microbiology Laboratories

Official Agency: Health Service Executive (HSE)

Date of Audit: December 2014

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NOVEMBER 2015

	To be completed by the FSAI			To be completed by the Agency		To be completed by the Agency & the FSAI through Service Contract Liaison process		
	Report Ref.	Finding Requiring Corrective Action	Relates to	Proposed Corrective Action	Proposed Completion Date	Update	Status	
							Open	Closed (include date closed out)
1.	4.1.1 (b) & 4.2.1 (b) & 4.3.1 (b)	<p>Organisational Structure of the Food Safety Laboratory Service (Official Food Microbiology Laboratories) within the Health Service Executive (HSE)</p> <p>The Food Safety Laboratory Service does not have a central management structure within the HSE for coordination and management of the group nationally. This does not meet the requirements of Section 4.2 of the HSE Service Contract with the FSAI (HSE Service Contract Revision 2 – 14/01/2013).</p>	HSE National Management			HSE Management response awaited		
2.	4.3.3 (a)	Sample Receipt, Handling and Analysis		The laboratory will contact the PEHOs in Galway, Mayo and Roscommon to request	Oct 2015	Closed		Oct 2015

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		The audit team observed instances where the temperature of samples at intake to the laboratory was missing on certain reports issued by the laboratory.	Galway University Hospital Public Health Laboratory (Official Food Microbiology Laboratory)	that all samples submitted have the temperature monitored during transport and this temperature is available for recording by the laboratory				
3.	4.1.3 (b)	<p>Timeframes for Analysis and Reporting of Results</p> <p>The audit team confirmed that on occasion, the four-week turnaround deadline referenced in SOP ALA 0018 (issue date 31.1.14) for reporting of microbiological results by the laboratory to the client, can be exceeded (this is primarily due to subcontracted confirmatory analysis).</p>	Sir Patrick Duns Public Analyst Laboratory (Official Food Microbiology Laboratory)	The laboratory will update SOP Public Analyst Laboratory A 0018 to include a timeline for the reissue of a report following the receipt of ancillary information/results such as serological characterisation of isolates from a subcontracted laboratory.	At next review of SOP (December 2015)			

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4.	4.2.3 (b)	<p>Timeframes for analysis and Reporting of Results</p> <p>Timeframes for testing and reporting of results have not been defined in the laboratory's procedures.</p>	<p>Limerick Public Health Laboratory (Official Food Microbiology Laboratory)</p>	<p><u>Documentation to be updated.</u></p> <p>Timeframe for analysis and reporting of results to be added to Quality Manual.</p> <p>Technical Requirements Controlled document reference QM_005</p> <p>Section 5.8.1.3 (page 23) Handling of Samples- The timeframe for testing and reporting of results is normally complete within three weeks. If tests are sub-contracted, a supplementary report is issued as soon as the report from the sub-contracting laboratory is received.</p>	15 October 2015	Closed		Oct 2015

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5.	4.3.3 (b)	<p>Timeframes for analysis and reporting of results</p> <p>Timeframes for testing and reporting of results have not been defined in the laboratory's procedures.</p>	Galway University Hospital Public Health Laboratory (Official Food Microbiology Laboratory)	A section will be added to the Laboratory Methods Manuals documenting the turnaround times for all test methods.	Completed Sept 2015	Closed		Sept 2015
6.	4.3.5	<p>Scope of Accreditation for the Performance of Official Controls</p> <p>Four yeast and mould samples had been tested in 2012. These results had not been reported in the Section 48(8) Annual Report for Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) issued to the FSAI for 2013.</p>	Galway University Hospital Public Health Laboratory (Official Food Microbiology Laboratory)	These samples were not reported because they were submitted by private customers and were extracted to the FSAI database in error. LIMS will be configured to ensure that private samples are not extracted.	Dec 2015			

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7.	4.2.6 (b)	<p>Method Validation</p> <p>In relation to the following accredited method, a validation report was not available on the day of the audit for: <i>Listeria monocytogenes</i> and other <i>Listeria species</i>: Enumeration and Confirmation FTM -TM7</p>	Limerick Public Health Laboratory (Official Food Microbiology Laboratory)	Submit validation report for <i>Listeria monocytogenes</i> and other <i>Listeria</i> species: Enumeration and Confirmation FTM-TM7E.	15 October 2015	Closed		Oct 2015
8.	4.1.6 (b)	<p>Method Validation</p> <p>A documented review that validations conducted for the following methods, i.e. in order to confirm that they continued to be appropriate and fit for purpose, had not been recorded recently as having taken place, i.e. not since at least 2006, i.e. for:</p>	Limerick Public Health Laboratory (Official Food Microbiology Laboratory)	<p>Introduce a new document Review of Test Method Validation into the Public Health Laboratory Limerick's Quality System.</p> <p>Modify ML20.10 Quality Audit Checklist: Test Methods and Methods Validation document to incorporate that the Review of Test Method Validation document</p>	15 October 2015	Closed		Oct 2015

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	<ul style="list-style-type: none"> • <i>Salmonella</i> species: Detection and Confirmation FTM - TM8 • <i>Campylobacter</i> species: Detection and confirmation FTM -TM4 • <i>E. coli O157</i>:Horizontal Method for Detection of <i>E. coli O157</i> FTM -TM12 		(covering all appropriate areas to ensure test method remains suitable and fit for purpose) has been updated for each test method being audited. Submit Review of Test Method validation document for <ul style="list-style-type: none"> • <i>Salmonella</i> species: Detection and Confirmation FTM - TM8 • <i>Campylobacter</i> species: Detection and confirmation FTM -TM4 • <i>E. coli O157</i>:Horizontal Method for Detection of <i>E. coli O157</i> 					
9.	4.1.6 (b)	Method Validation A documented review that the UM established for methods remains suitable/appropriate,	Limerick Public Health Laboratory	Include in the above Review of Test Method Validation document a review of the UM established for methods.	15 October 2015	Closed		Oct 2015

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		was not being routinely recorded by the laboratory.	(Official Food Microbiology Laboratory)	This will ensure that the UM remains suitable and appropriate for all test methods				
10.	4.1.6 (d)	<p>Subcontracting of Methods of Analysis</p> <p>The audit team observed that in a number of instances, <i>Listeria</i> isolates were not sent to the DAFM National Reference Laboratory in Backweston, which is designated for this function, in accordance with Ireland's National Control Plan 2012 – 16, i.e. as part of Regulation 882/2004 requirements.</p>	Sir Patrick Duns Public Analyst Laboratory (Official Food Microbiology Laboratory)	<p>The laboratory agreed to send these to the National Reference Laboratory following this audit finding.</p> <p>The laboratory sent the isolates to the National Reference Laboratory. The laboratory LIMS system was updated to include a prompt to initiate dispatch to the National Reference Laboratory when <i>Listeria</i> isolates are found in the future.</p>	Completed 21 st of January 2015	Closed		Jan 2015

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11.	4.1.6 (d)	<p>Subcontracting of Methods of Analysis</p> <p>The audit team observed that in a number of instances, <i>Listeria</i> isolates were not sent to the DAFM National Reference Laboratory in Backweston, i.e. which is designated for this function, in accordance with Ireland's National Control Plan 2012 – 16, as part of Regulation 882/2004, requirements. Similarly, Staphylococcal toxin confirmatory samples were also not sent to the DAFM National Reference Laboratory in Backweston, i.e. which is designated for this function, in accordance with Ireland's National Control Plan 2012 – 16, as part of Regulation 882/2004, requirements.</p>	Galway University Hospital Public Health Laboratory (Official Food Microbiology Laboratory)	The laboratory will send all Coagulase positive <i>Staphylococci</i> isolates and <i>Listeria</i> isolates to the DAFM National Reference Laboratory.	Completed Sept 2015	Closed		Sept 2015

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12.	4.1.7 (d)	<p>Reporting of Data to the FSAI</p> <p>The audit team confirmed that Sir Patrick Duns Public Analyst Laboratory/Official Food Microbiology Laboratory had configured their LIMS extracts for both sample and reporting designations in accordance with the data transmissions/extracts format requested by the FSAI.</p> <p>The LIMS extract however, does not include subcontracted tests, e.g. the subcontracting of test isolates to the National Reference Laboratory.</p>	Sir Patrick Duns Public Analyst Laboratory (Official Food Microbiology Laboratory)	The laboratory has worked in conjunction with the FSAI Data Section to implement an effective solution through LIMS configuration updates. A local solution has been implemented.		<p>Specific item completed locally.</p> <p>Principle established for future needs.</p> <p>Work in Progress.</p>		
13.	4.2.7 (b)	<p>Reporting of Data to the FSAI</p> <p>The audit team confirmed that Limerick Official Food</p>	Limerick Public Health	Limerick to configure Public Health Laboratory Limerick LIMS extracts for both sample and	Work in progress			

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		Microbiology Laboratory/Official Food Microbiology Laboratory had not yet configured their LIMS extracts for both sample and reporting designations in accordance with data transmissions/extracts format requested by the FSAI.	Laboratory (Official Food Microbiology Laboratory)	reporting designations in accordance with data transmissions/extracts format requested by the FSAI.				
14.	4.3.7 (b)	<p>Reporting of Data to the FSAI</p> <p>The audit team confirmed that Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) had configured its LIMS extracts for sample designation but had yet to complete this for report designation.</p> <p>The LIMS extracts however, do not always include</p>	Galway University Hospital Public Health Laboratory (Official Food Microbiology Laboratory)	<p>The laboratory will configure LIMS to designate test, sample and batch results. The LIMS extract will be configured to include subcontracted tests.</p> <p>These actions are currently in progress and are being carried out as part of the terms of reference of the LIMS</p>	June 2016			

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		subcontracted tests, e.g. the subcontracting of test isolates to the National Reference Laboratory.		Users Group and is currently ongoing				
15.	4.1.9	<p>Reporting, Designation and Certification</p> <p>Variation in the application of UM to reported results for 2073/2005 analysis was observed when comparing the three Official Food Microbiology Laboratories audited, which could not be considered as fully consistent.</p> <ul style="list-style-type: none"> Sir Patrick Duns Public Analyst Laboratory/Official Food Microbiology Laboratories apply a UM to the result designation and the UM is subtracted as part 	Official Food Microbiology Laboratory	<p>Work in progress.</p> <p>Timeline and approach to be discussed at next Official Food Microbiology Laboratories meeting (November 2015).</p>	Q1 2016			

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		of the quantification and determination of the result reported. <ul style="list-style-type: none"> • Limerick Official Food Microbiology Laboratory/Public Health Laboratory does not apply a UM to the result designation for 2073/2005 quantitative testing. • Galway University Hospital (Official Food Microbiology Laboratory/Public Health Laboratory) does not apply a UM to the result designation for 2073/2005 quantitative testing. 						

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16.	4.1.10 (d) & 4.1.10 (d) & 4.1.10 (d)	<p>Internal and External Audits</p> <p>The audit team observed that an internal audit system as part of the HSE's compliance with the requirements of Article 4.6 of Regulation 882/2004 is not in place.</p> <p>This also does not fully comply with Schedule 2 Section 1.20 of the FSAI Service Contract and Appendix 1 (1.20) of the FSAI Work Programme.</p>	HSE National Management			HSE Management response awaited		
17.	4.1.10 (d)	<p>Internal and External Audits</p> <p>The laboratory's internal audit schedule had fallen behind for 2014, i.e. for vertical audits and consequently not all scheduled Internal audits had been conducted.</p>	Sir Patrick Duns Public Analyst Laboratory (Official Food Microbiology Laboratory)	The laboratory carried out supplementary audits in the areas that had not been addressed to correct the failings identified.	Complete 23 rd of July 2015	Closed		July 2015

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18.	4.1.10 (d)	<p>Internal and External Audits</p> <p>All regularly used methods are subject to test witnessed audits over a period of three years. Less routinely used methods however are not reviewed as frequently, e.g. <i>Campylobacter</i>, Public Analyst Laboratory SOP 4003.</p>	Sir Patrick Duns Public Analyst Laboratory (Official Food Microbiology Laboratory)	The <i>Campylobacter</i> parameter was included in an audit to address the failure. In addition, stored queries were developed in the LIMS system to improve oversight of the progress of the internal audit program which is implemented through LIMS in this laboratory.	Complete 11 th of February 2015	Closed		Feb 2015
19.	4.2.10 (d)	<p>Internal and External Audits</p> <p>All regularly used methods are subject to audits. The audit team observed however, that non-accredited tests may not be subject to regular internal audits.</p> <p>Consequently, the <i>E. coli</i> O26, which was not yet fully</p>	Limerick Public Health Laboratory (Official Food Microbiology Laboratory)	<p>Non-accredited tests to be included in Test Method Audit Schedule ML148 document.</p> <p>Consequently, <i>E.coli</i> O26 will be subject to audits similar to all regularly used methods.</p>	15 October 2015	Closed		Oct 2015

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		accredited, was not subject to audits in 2013 and 2014.						
20.	4.3.10 (d)	Internal and External Audits The audit team confirmed that for non-accredited tests/less frequently used methods, e.g. in the case of yeast and mould testing, these were not subject to the same degree of internal or external audit verification.	Galway University Hospital Public Health Laboratory (Official Food Microbiology Laboratory)	The laboratory will no longer carry out non-accredited testing for samples submitted as part of the FSAI contract and will therefore, not require any internal or external verification.	Completed Sept 2015	Closed		Sept 2015



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