

## 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  
(Updated March 2020)



## CORRECTIVE ACTION PLAN

This Corrective Action Plan describes audit findings requiring corrective action, documents responsibility for addressing the findings, and describes progress on the closeout of actions.

**Audit:** Audit of Compliance of Official Food Microbiology Laboratories

**Official agency:** Health Service Executive (HSE)

**Date of audit:** December 2014

### CORRECTIVE ACTION PLAN

	To be completed by the FSAI			To be completed by the agency		To be completed by the agency and the FSAI through service contract liaison process		
	Report reference number	Finding requiring corrective action	Relates to	Proposed corrective action	Proposed completion date	Updated Sept 2016	Status	
							Open	Closed (include date closed out)
1.	4.1.1 (b) & 4.2.1 (b) & 4.3.1 (b)	<p><b>Organisational Structure of the Food Safety Laboratory Service (OFMLs) within the HSE</b></p> <p>The FSLS does not have a central management structure, within the HSE, for co-ordination 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.	Open	

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2.	4.3.3 (a)	<p><b>Sample Receipt, Handling and Analysis</b></p> <p>The audit team observed instances where the temperature of samples at intake to the laboratory were missing on certain reports issued by the laboratory.</p>	GUH PHL (OFML)	The laboratory will contact the PEHOs in Galway, Mayo and Roscommon to request that <b>all</b> samples submitted have the temperature monitored during transport and this temperature is available for recording by the laboratory.	Oct 2015	Closed		Sept 2018

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3.		<p><b><i>Timeframes for analysis and reporting of results</i></b></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>	SPD PAL (OFML)	The laboratory will update SOP PALA 0018 to include a timeline for the reissue of a report following the receipt of ancillary information/results such as serological characterization of isolates from a subcontracted laboratory.	At next review of SOP (December 2015).	Closed		August 2016

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4.	4.2.3 (b)	<p><b><i>Timeframes for analysis and reporting of results</i></b></p> <p>Timeframes for testing and reporting of results have not been defined in the laboratory's procedures.</p>	LM PHL (OFML)	<p><b><u>Documentation to be updated.</u></b></p> <p>Timeframe for analysis and reporting of results to be added to Quality Manual.</p> <p><b>Technical Requirements.</b> Controlled document reference <b>QM 005</b></p> <p>Section 5.8.1.3 (page 23) <b>Handling of samples -</b> 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 subcontracting laboratory is received.</p>	15 October 2015	Closed		Oct 2015

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5	4.3.3 (b)	<p><b>Timeframes for analysis and reporting of results</b></p> <p><i>Timeframes for testing and reporting of results</i> have not been defined in the laboratory's procedures.</p>	<p>GUH PHL (OFML)</p>	<p>A section will be added to the Laboratory Methods Manuals documenting the turnaround times for all test methods.</p>	<p>Completed Sept 2015</p>	<p>Closed</p>		<p>Sept 2015</p>
6.	4.3.5	<p><b>Scope of Accreditation for the Performance of Official Controls</b></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 GUH (OFML/PHL) issued to FSAI for 2013.</p>	<p>GUH PHL (OFML)</p>	<p>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.</p>	<p>Dec 2015</p>	<p>Closed</p>		<p>April 2015</p>

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7.	4.2.6 (b)	<p><b>Method Validation</b></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</i> species: <i>Enumeration and Confirmation FTM -TM7</i>.</p>	LM PHL (OFML)	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



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8.	4.1.6 (b)	<p><b>Method Validation</b></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> <ul style="list-style-type: none"> <li>• <i>Salmonella species: Detection and Confirmation FTM - TM8</i></li> <li>• <i>Campylobacter species: Detection and confirmation FTM -TM4</i></li> <li>• <i>E. coli O157: Horizontal Method for Detection of E. coli 0157 FTM -TM12.</i></li> </ul>	LM PHL (OFML)	<p>Introduce a new document <b>Review of Test Method validation</b> into the PHL Limerick's quality system.</p> <p>Modify ML20.10 <b>Quality Audit Checklist: Test methods and methods validation</b> document to incorporate that the <b>Review of Test Method validation</b> document (covering all appropriate areas to ensure Test Method remains suitable and fit for purpose) has been updated for each Test Method being audited.</p> <p><b>Submit Review of Test Method validation</b> document for</p> <ul style="list-style-type: none"> <li>• Salmonella species: Detection and Confirmation FTM - TM8</li> <li>• Campylobacter species: Detection and confirmation FTM -TM4</li> <li>• E. coli O157:Horizontal Method for Detection of E. coli 0157.</li> </ul>	15 October 2015	Closed		Oct 2015
9.	4.1.6(b)	<p><b>Method Validation</b></p> <p>A documented review that the uncertainty of measurement (UM)</p>	LM PHL (OFML)	Include in the above <b>Review of Test Method validation</b> document a review of the uncertainty	15 October 2015	Closed		Oct 2015

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		established for methods, remains suitable/appropriate, was not being routinely recorded by the laboratory.		of measurement (UM) established for methods. This will ensure that the UM remains suitable and appropriate for all test methods.				
10.	4.1.6 (d)	<p><b>Subcontracting of Methods of Analysis</b></p> <p>The audit team observed that in a number of instances, <i>Listeria</i> isolates were not sent to the DAFM NRL 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>	SPD PAL (OFML)	The laboratory agreed to send these to the NRL following this audit finding. The laboratory sent the isolates to the NRL. The laboratory LIMS system was updated to include a prompt to initiate dispatch to the NRL when <i>Listeria</i> isolates are found in the future.	Completed 21 January 2015	Closed		Jan 2015

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11.	4.1.6 (d)	<p><b>Subcontracting of Methods of Analysis</b></p> <p>The audit team observed that in a number of instances <i>Listeria</i> isolates were not sent to the DAFM NRL 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> <p>Similarly, Staphylococcal toxin confirmatory samples were also not sent to the DAFM NRL 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>	GUH PHL (OFML)	The laboratory will send all Coagulase Positive Staphylococci isolates and <i>Listeria</i> isolates to the DAFM NRL.	Completed Sept 2015	Closed		Sept 2015

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12.	4.1.7 (d)	<p><b>Reporting of Data to the FSAI</b></p> <p>The audit team confirmed that SPD PAL/OFML had configured its LIMS extracts for both sample and reporting designations in accordance with the data transmissions/extracts format, requested by the FSAI. The LIMS extract however does not include subcontracted tests, e.g. the subcontracting of test isolates to the NRL.</p>	SPD PAL (OFML)	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>	Closed		Sept 2015
13.	4.2.7 (b)	<p><b>Reporting of Data to the FSAI</b></p> <p>The audit team confirmed that LM OFML/OFML had not yet configured their LIMS extracts for both sample and reporting designations in accordance with data transmissions/extracts format requested by FSAI.</p>	LM PHL (OFML)	LM to configure PHL Limerick LIMS extracts for both sample and reporting designations in accordance with data transmissions/extracts format requested by FSAI.		Closed		Sept 2015

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14.	4.3.7 (b)	<p><b>Reporting of Data to FSAI</b></p> <p>The audit team confirmed that GUH (OFML/PHL) had configured its LIMS extracts for sample designation but had yet to complete this for report designation. The LIMS extracts however, do not always include subcontracted tests, e.g. the subcontracting of test isolates to the NRL.</p>	GUH PHL (OFML)	The laboratory will configure LIMS to designate test, sample and batch results. The LIMS Extract will be configured to include subcontracted tests. These actions are currently in progress and are being carried out as part of the terms of reference of the LIMS Users group and is currently ongoing.	April 2021		Open	

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15.	4.1.9	<p><b>Reporting, designation and Certification</b></p> <p>Variation in the application of uncertainty of measurement (UM) to reported results for 2073/2005 analysis was observed when comparing the three OFMLs audited, which could not be considered as fully consistent.</p> <ul style="list-style-type: none"> <li>• SPD PAL/OFML apply an uncertainty of measurement (UM) to the result designation and the UM is subtracted as part of the quantification and determination of the result reported.</li> <li>• LM OFML/PHL do not apply an uncertainty of measurement (UM) to the result designation for 2073/2005 quantitative testing.</li> <li>• GUH (OFML/PHL) do not apply an uncertainty of measurement (UM) to the result designation for 2073/2005 quantitative testing.</li> </ul>	OFMLs	<p>Work in progress.</p> <p>Timeline and approach to be discussed at next OFML meeting (November 2015).</p>	Q1 2016	Closed		December 2015
16.	4.1.10 (d) & 4.1.10 (d)	<p><b>Internal and External Audits</b></p> <p>The audit team observed that an internal audit system as part of the</p>	HSE National Management			HSE management response	Open	

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	& 4.1.10 (d)	HSE's compliance with the requirements of article 4.6 of regulation 882/2004 is not in place.  This also does not fully comply with schedule 2 section 1.20 of the FSAI service contract and appendix 1 (1.20) of the FSAI Work Programme.				awaited.		
17.	4.1.10 (d)	<b>Internal and External Audits</b>  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.	SPD PAL (OFML)	The laboratory carried out supplementary audits in the areas that had not been addressed to correct the failings identified.	July 2015	Closed		July 2015

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18.	4.1.10 (d)	<p><b>Internal and External Audits</b></p> <p>All regularly used methods are subject to test witnessed audits over a period of 3 years. Less routinely used methods however are not reviewed as frequently, e.g. <i>Campylobacter</i> PALM SOP 4003.</p>	SPD PAL (OFML)	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.	February 2015	Closed		Feb 2015
19.	4.2.10 (d)	<p><b>Internal and External Audits</b></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. Consequently, the <i>E. coli</i> O26, which was not yet fully accredited, was not subject to audits in 2013 and 2014.</p>	LM PHL (OFML)	Non-accredited tests to be included in Test Method audit schedule ML148 document. Consequently, <i>E. coli</i> O26 will be subject to audits similar to all regularly used methods.	October 2015	Closed		Oct 2015



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20.	4.3.10 (d)	<p><b>Internal and External Audits</b></p> <p>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.</p>	GUH PHL (OFML)	The laboratory will no longer carry out nonaccredited testing for samples submitted as part of the FSAI contract and will therefore not require any internal or external verification.	Sept 2015	Closed		Sept 2015




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