

AUDIT REPORT

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

CORRECTIVE ACTION PLAN

Updated March 2021



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

Official agency: Health Service Executive

Date of audit: November to December 2018

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	Update	Status	
							Open	Closed (include date closed out)
1	4.1.2 4.2.2 4.3.2	There is no national structure within the HSE, for co-ordination and management of the Food Safety Laboratory Service, 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 Food Safety Laboratory Service (FSLs) in 2014 by FSAI).	HSE National Management			HSE management response awaited.	Open	

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2	4.2.12	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	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 audit, Galway PAL conducted a cause analysis which included assessment of impact on results issued. Galway PAL advised that there was no further impact on results issued for similar tests, outside of this incident.	September 2019	Galway PAL indicated that the error related to the range referred to in the certificate (not to the test result) and an amended certificate was issued.	Closed	18.09.19
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3	4.3.7	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, where the LOQ is at or above the maximum permitted level for some matrices particularly infant formula 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	<p>Lower the LOQ for Cadmium in liquid formula to meet the requirements of Reg (EC) 1881/2006</p> <p>While it will be possible to lower the LOQ for Cadmium in powdered formula to less than the maximum permitted level, it will not be possible to meet the requirements of Reg (EU) 2016/582, i.e.LOQ≤0.004mg/Kg</p> <p>Increase the range of analysis of the mercury method to include the MLs specified in Reg. (EC) 1881/2006</p>	<p>August 2021</p> <p>August 2021</p> <p>August 2021</p>			
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