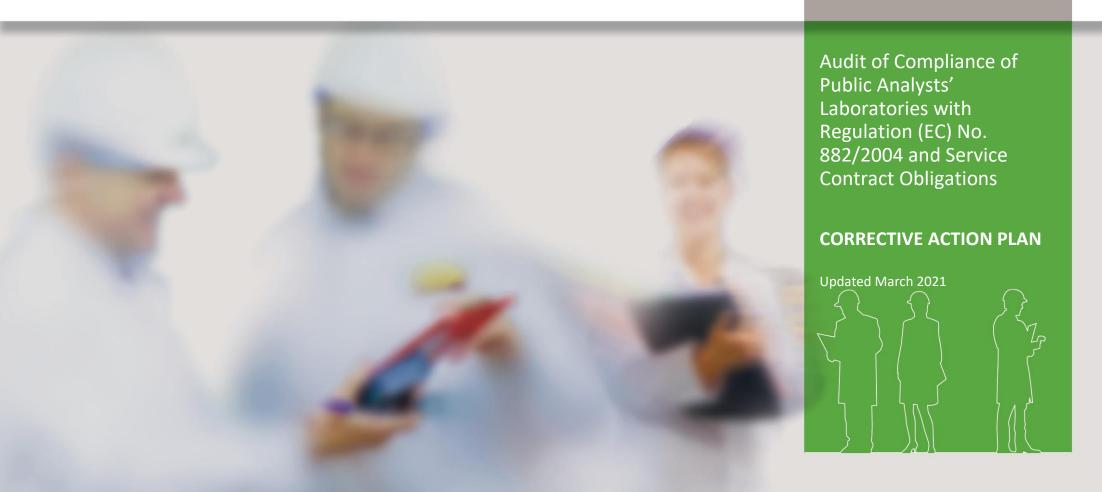


# AUDIT REPORT



OCTOBER 2019

### **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

OCTOBER 2019

## **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		
	Donout				Proposed completion date	Update	Status	
	Report reference number	Finding requiring corrective action	Relates to	Proposed corrective action			Open	Closed (include date closed out)
1	4.1.2	There is no national structure within the HSE, for co-ordination and management	HSE National			HSE management response awaited.	Open	
	4.2.2	of the Food Safety Laboratory Service, which does not meet the requirements of	Management					
	4.3.2	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).						

## **CORRECTIVE ACTION PLAN**

2	4.2.12	An error was noted in respect of a	Galway PAL	Galway PAL has committed to	September	Galway PAL	Closed	18.09.19
		certificate of analysis for sodium in		undertake corrective actions	2019	indicated that the		
		dietary food for special medical purposes		(such as issuing an amended		error related to the		
		issued in April 2018.		certificate of analysis,		range referred to in		
				communication with the		the certificate (not		
				sampling officer, re-sampling		to the test result)		
				and testing). During the audit,		and an amended		
				Galway PAL conducted a cause		certificate was		
				analysis which included		issued.		
				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.				

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## **CORRECTIVE ACTION PLAN**

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	Cork PAL	Lower the LOQ for Cadmium in liquid formula to meet the requirements of Reg (EC)	August 2021		
		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.		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 Increase the range of analysis of the mercury method to include the MLs specified in Reg. (EC) 1881/2006	August 2021 August 2021		



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