

## AUDIT REPORT

Audit of Official Controls  
in Food Supplement  
Establishments supervised  
by Environmental Health  
Officers in the Health  
Service Executive

### **CORRECTIVE ACTION PLAN**

July 2014  
(All corrective actions closed -  
December 2017)



## 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:** Official Controls in Food Supplement Establishments supervised by the Environmental Health Officers in the Health Service Executive

**Official agency:** Health Service Executive - Environmental Health Service

**Date of audit:** June 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	Proposed corrective action	Proposed completion date	Updated Sept 2016	Status	
						Open	Closed (include date closed out)
1	4.2	<p>The list of food supplement notifications produced by the FSAI from the notification database was not accurate.</p> <p>Some PEHO offices were using the notifications list to identify establishments for supervision and to facilitate checks in food supplement establishments regarding label notifications. However, three PEHO offices were not reviewing the information provided to facilitate official controls.</p>	<p>FSAI response: The FSAI will review the reasons for the inaccuracies in the food supplement notification lists and instigate a project in 2014 to resolve any problems in the electronic systems and processes used within the FSAI.</p> <p>EHS response: Once the FSAI has resolved the inaccuracies in the food supplements notifications list, it will circulate the list for the purpose of advising the EHS of potential food business operators.</p>		<p>Information on food supplements notified to the FSAI is now provided to EHOs on request as the current supplements database is not suitable for producing general reports.</p> <p>The FSAI are reviewing options for future development of a new supplements database with additional functionality.</p>		January 2016
2	4.2	One office audited was not meeting inspection targets as	HSE response: This finding is not related		In 2014 and 2015, service contract national targets		March 2016

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		set down in the Business Plan.	to the food supplement establishments audited.  National inspection targets agreed with the FSAI were met in 2013. We will agree revised national targets with FSAI for 2014.		were met. Achievement of inspection targets in local areas is dependent on available resources which vary from year to year due to permanent and temporary deficits.		
3	4.4	Inconsistencies in how food business operators are risk profiled were identified.	HSE response: The HSE is forwarding the risk profiling queries to the FSAI/HSE Consistency Group for their consideration. This relates in the main to the interpretation of whether food supplements should be considered high risk foods.	Dec 2014	An amended approach to risk profiling has been agreed and is being incorporated into EHS processes.		August 2016
4	4.5	The <i>aide memoire</i> and checklist were not used in some distributors and in one manufacturer	HSE response: The usage of the aide memoire for manufacturers and distributors on a phased basis has been included in the 2014 Service Contract Work Plan Table 2.	April 2014	HSE inspections in 2015 & 2016 incorporate the use of the <i>Aide Memoir</i> .		February 2015

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5	4.6	<p>Template letters are not always used when issuing reports to food business operators.</p> <p>Inspection outcomes are not always applied in line with the FSAI Guidance Note 1 (Revision 2).</p>	<p>HSE response: Action taken: EHS audit participants have advised that template letters are now in use.</p> <p>The HSE has established a HACCP consistency group which will look at HACCP related inspection outcomes.</p>	<p>April 2014</p> <p>December 2014</p>	<p>The EHS has assessed all manufacturers for compliance with Article 5 of Regulation 852/2004 and inspection outcomes are in line with FSAI Guidance Note No. 1 (Revision 2).</p>		<p>December 2017</p>
6	4.7	<p>Some official control inspections did not identify non-compliances in food supplement establishments demonstrating a need for further training of officers.</p>	<p>FSAI response: The FSAI to work with the EHS in 2014 to develop targeted training for officers addressing the issues identified in this report.</p> <p>EHS response: Food supplement training has been included in Service Contract Work Plan Table 1 for 2014.</p>	<p>December 2014</p>	<p>Food supplement training carried out in 2014. Service contract work plan includes specific targets for supplement controls which EHOs are implementing.</p>		<p>September 2014</p>
7	4.8	<p>Effectiveness is reviewed differently at PEHO offices.</p> <p>Internal audits for assessing performance of official controls, i.e. in order to comply</p>	<p>EHS response: Clause 1.20 Internal Audit of the FSAI HSE Service Contract states: <i>'The Official Agency shall carry</i></p>		<p>The HSE has a national document on HSE approach of verification of the effectiveness of official controls as</p>		<p>April 2016</p>

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		<p>with the requirements of Article 4(6) of 882/2004, were not taking place at the time of the FSAI audit.</p>	<p><i>out internal audits or may have external audits carried out, in compliance with the requirements of Article 4(6) of Regulation 882/2004 and in accordance with the guidelines contained in Commission Decision 2006/677/EC.</i> Article 4(6) of Regulation 882/2004 states that <i>“Competent Authorities shall carry out internal audits or may have external audits carried out.”</i></p> <p>The FSAI Audit Charter states that <i>‘FSAI audits of official controls are external audits of these competent authorities.’</i></p> <p>The MANCP says that <i>‘Competent authorities are subject to external audits of official controls by the following bodies:</i></p> <ul style="list-style-type: none"> <li>• <i>FSAI in accordance with Schedule 5 of the</i></li> </ul>		<p>required by Article 8(3) of Regulation 882/2004.</p> <p>The HSE EHS Quality Assurance operational unit established incorporating internal audit. Initial audit underway.</p>		<p>August 2016</p>
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			<i>service contracts.</i>				
8	5.6	The official control system in place for assessing labels is not fully effective.	<p>FSAI response: The FSAI will review reasons for not copying food business operators' letters to EHS with a view to implementing an effective process of notification in the near future.</p> <p>HSE response: The HSE will liaise with the FSAI following its review of their process.</p>		The FSAI has implemented procedures to systematically inform the HSE on non-compliances identified during checks on foods supplements notified to the FSAI.		July 2016
9	5.0	The non-compliances identified as part of the on-site verification activity, e.g. no procedures based on HACCP should be closed out by the Environmental Health Service in conjunction with the food business operators.	<p>EHS response: Relevant activities have been included in Service Contract Work Plan Table 2 for 2014 which is due to be signed off in April 2014.</p>	April 2014	All food business operator food supplement audit findings closed.		July 2016




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