

AUDIT REPORT

Audit Report of Official Controls conducted by the **Health Service Executive** (HSE) in Category 2 Classified Food Business Operations **CORRECTIVE ACTION PLAN** MAY 2014 (All corrective actions closed September 2016)

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 Official Controls conducted by the HSE in Category Two Classified Food Business Operations

Official agency: Health Service Executive - Environmental Health Service

Date of audit: December 2012

| | To be completed by the FSAI | | To be completed by the | agency | To be completed by the agency and the FSA through service contract liaison process | | |
|---|-----------------------------|--|--|-----------------|--|--------|--|
| | Report Finding requiring | | Proposed | | St | Status | |
| | reference number | Finding requiring corrective action | Proposed corrective action | completion date | Updated Sept 2016 | Open | Closed (include date closed out) |
| 1 | 4.3 Table 3 | The official agency (HSE) must provide staff and resources at a level that will deliver the service outputs/activities defined in Schedule 2 of the Contract and meet the operational requirements of the legislation to be complied with. A significant disparity exists, at local level, when comparing the available resources (i.e. within PEHO offices) and the official control targets to be delivered, in accordance with the requirements of FSAI GN1. | The HSE FSAI service contract states that 'Both parties to the Service Contract accept that staffing levels over the period of this contract will decrease. Consequently, enforcement will have to be considered in the context of available resources and may require the objectives and targets set out in this schedule to be reviewed and reprioritised. To this end the Official Agency and the Authority will review and amend objectives and targets set under this contract, as part of the agreement of the annual work programme, to take account of available resources.' Staffing levels have been decreasing since 2007. The acceptance by the FSAI that | | In 2014 and 2015, service contract national targets 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. | | March 2016 |

| | | | staffing levels will decrease is not reflected in the audit report. The HSE operates within the constraints of the Public Sector Moratorium on recruitment and has seen a steady reduction in staffing numbers in recent years. Consequently, the HSE EHS has had to prioritise its activities in accordance with these staffing reductions. Targets for inspection numbers were agreed in the 2013 HSE FSAI Service Contract Work Plan. The target of 33,000 inspections was met. Nationally consistent targets were set by the EHS in 2013. Resources will continue to be managed to meet service contract commitments in the light of staffing reductions. | | |
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| 2 | 4.4 | Not all premises were being inspected in accordance with the standard or minimum frequencies as required by FSAI GN 1. | The scope of the audit was Category 2 food business operators. The corrective action taken during 2013 was as follows. The | In 2014 and 2015, service contract national targets were met. Achievement of inspection targets in | March 2016 |

| | | In two of the four PEHO offices not all Category 3 risk classified food business operator establishments were being inspected in accordance with the inspection target frequencies to be achieved as per FSAI GN 1 and also with the EHS Environmental Health Business Plan for 2012. For Category 4 and 5 establishments, the minimum target frequencies were in general not being met within each of the four PEHO offices. This was primarily due to the focus on higher risk food business operator establishments and lack of available resources. | agreed 2013 FSAI HSE Service Contract Work Plan provided for inspection of Category 3 premises outside of the minimum and standard frequencies set in FSAI GN 1 Document. The corrective action taken during 2013 was as follows. The agreed 2013 FSAI/HSE Service Contract Work Plan provided for a minimum target inspection figure of 33,000 programmed and programmed surveillance inspections with inspection priority to be given to the highest categories of risk premises. This target was achieved. | local areas is dependent on available resources which vary from year to year due to permanent and temporary deficits. | |
|---|-----|--|--|---|------------|
| 3 | 4.6 | The official agency is required to maintain an up-to-date national list of all food establishments which are under HSE supervision. During a review of food business operator establishments two lists had been provided to the FSAI by the EHS. | Corrective action was taken in 2013 when the FSAI was provided with an updated list. A more accurate version of the list was provided to the FSAI in 2014. | | April 2014 |

| | | The audit team noted that, for several Category 2 classified food business operator establishments, some were not present on either of the two lists provided and/or on several occasions they had been recorded more than once which resulted in duplication of premises numbers. Consequently, the lists provided could not be considered as entirely meeting the requirements of Article 31 of Regulation 882/2004 and the FSAI Service Contract. | | | |
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| 4 | 4.7 | Although EHS protocols were generally being adhered to, certain documented procedures/protocols were however, not being fully complied with (see Section 4.7 of report). | The only protocol identified as not being adhered to in December 2012 was Protocol 39. The HSE West PEHO has confirmed that the issue was rectified immediately after the audit and that the protocol was adhered to in 2013. In relation to HSE DML - Probe thermometers used by EHOs were calibrated externally and there was a calibration control | | January 2014 |

| | | | sheet maintained in line with Protocol 39 to ensure equipment in use is calibrated. There was an up to date calibration certificate and completed log for all equipment in use at the time of the audit. In relation to HSE South - The calibration log was maintained as per the procedure. 1 officer had 2 probes in their possession which were out of status and which had not been used. Reminders had been issued via email to present the thermometers for calibration (email evidence provided to the auditors). HSE DML & South were compliant with protocol 39 at the time of the Audit and all three PEHOs have confirmed that protocol 39 was adhered to in 2013. | | |
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| 5 | 4.8 | Inspections carried out in Category 2 establishments were as a general rule being followed up in accordance with the requirements of FSAI GN 1, Regulation 882/2004 | Section 4.8 does not specifically identify any deficiencies in relation to Article 9, Article 54 or GN 1. | The HSE has verified that this has been closed through checks on Category 2 inspection files. | April 2016 |

| | | and EHS protocols, with the exception of certain deficiencies (see section 4.8 of report). | Timelines – Timelines in correspondence are required as a result of specific inspection outcomes in EHS Protocol 3. They are not a requirement of 882/2004 or GN 1. PEHOs will verify if the audited files had inspection outcomes which required timelines. Documenting follow up on close out of noncompliances – All noncompliances from a previous inspection are now automatically included in the next inspection record. | Non-compliant areas from a previous inspection are now automatically included in the next inspection record. | |
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| 6 | 4.9 | A national training plan was developed in 2012 but had yet to be fully implemented at the time of the FSAI audit as specified in the Service Contract. | Corrective action was taken in 2013. The national training plan was implemented in 2013. The FSAI was given a copy. | | February 2013 |
| 7 | 4.10 | In the DML office, the audit team were informed that an informal approach to assess effectiveness was in place. At | An external audit was carried out by the EU Food and Veterinary Office (FVO) on | The HSE has provided its document for verification of the | April 2016 |

| | | the time of the audit, due to the general lack of evidence of reviews for this office, this process could not be considered as effective and did not fulfil the requirements of Article 8(3) of Regulation 882/2004. A standardised approach for conducting reviews within the EHS PEHO offices, nationally, could not be considered to be fully in place. A review of the effectiveness of EHS official controls at national level, although planned, could not be considered to have taken place at the time of the FSAI audit. | the verification of systems in place to implement Article 8(3) of Regulation 882/2004 in October 2013. The FVO audit report (2013 -6859) stated that the 'EHS has put in place procedures to implement Articles 8(3) (a) and (b) of Regulation (EC) No 882/2004 and continues to develop these procedures.' The HSE considers that variation in approaches to review does not demonstrate a lack of effectiveness. As per FVO audit, EHS continues to develop its procedures on the review of effectiveness. | effectiveness of official controls as required by Article 8(3) of Regulation 882/2004. | |
|---|------|---|--|---|-------------|
| 8 | 4.10 | At national level, a system of internal audits was not in place. Consequently, the EHS was currently not complying with either the requirements of Article 4(6) of Regulation (EC) No. 882/2004 and Section | Clause 1.20 Internal Audit of the FSAI HSE Service Contract states 'The Official Agency shall carry 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 | The HSE EHS Quality Assurance operational unit established incorporating internal audit. Initial audit underway. | August 2016 |

| 1.20 of the service contract. | contained in Commission Decision 2006/677/EC. |
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| | Article 4 (6) of Regulation 882/2004 states that "Competent Authorities shall carry out internal audits or may have external audits carried out." |
| | The FSAI Audit Charter states that 'FSAI audits of official controls are external audits of these competent authorities.' |
| | The HSE considers that the requirements of the HSE FSAI Service Contract and of Article 4 (6) of Regulation 882/2004 have been met. No evidence is presented in the audit report to support the statement that there was a weakness in HSE official controls due to the absence of a formal internal audit function. |
| | The audit report statement that 'FSAI audits do not substitute for the competent authority's responsibility to implement the requirements of Regulation |

| | | | (EC) No. 882/2004 'is in direct contradiction to the FSAIs statement to the FVO and the FSAI Audit Charter. Notwithstanding our position outlined above the HSE EHS intends to develop an internal audit function as soon as possible. | | |
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| 9 | 5.0 | The non-compliances identified as part of the on-site verification activity should be closed out by EHS HSE in conjunction with the food business operators | The closing meeting of the audit was held with the FSAI in December 2012. The draft report was issued December 2013. The time between the audit and issuing of the report has meant that the food business operators that were audited have been inspected by the HSE since that date. | The HSE has confirmed that the non compliances were closed out. | December 2013 |



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