

AUDIT  
REPORT

Audit Report of Official  
Controls conducted by  
the Health Service Executive  
(HSE) in Category 2 Classified  
Food Business Operations

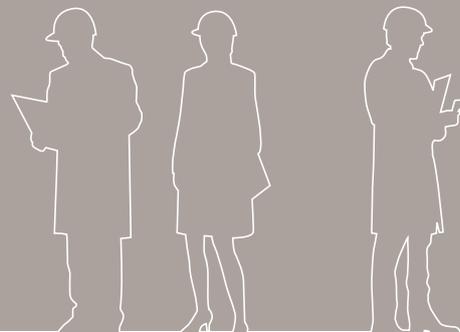
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## **1. GLOSSARY**

|       |   |
|-------|---|
| EHO   | Environmental Health Officer                |
| FSAI  | Food Safety Authority of Ireland            |
| HACCP | Hazard Analysis Critical Control Point      |
| HSE   | Health Service Executive                    |
| PEHO  | Principal Environmental Health Officer      |
| RCEHO | Regional Chief Environmental Health Officer |
| SEHO  | Senior Environmental Health Officer         |

## **2. EXECUTIVE SUMMARY**

The Food Safety Authority of Ireland (FSAI) completed an audit of the food safety controls performed by the Environmental Health Service of the Health Service Executive (HSE), with a particular focus on high-risk food establishments, i.e. Category 2<sup>1</sup> premises, which had been risk classified in accordance with FSAI *Guidance Note No. 1* requirements. The audit was undertaken as part of the planned programme of audits carried out by the FSAI to determine the level of compliance with Regulation (EC) No 882/2004 (Official Controls) and the Service Contract in place between the HSE and the FSAI.

The Environmental Health Service is managed nationally by the Assistant National Director for Environmental Health and Emergency Management, four Regional Chief Environmental Health Officers (RCEHOs) and 32 Principal Environmental Health Officers (PEHOs). Collectively, the national management team for the Environmental Health Service consists of the Assistant National Director for Environmental Health and Emergency Management and four RCEHOs. Discussions and interviews with the national management team took place, i.e. with RCEHOs, in relation to the organisation, planning, delivery and review of official controls as part of the service delivery requirements to be performed nationally.

At local level, an assessment of the management and delivery of Environmental Health Service official controls was carried out. This included visits to four PEHO offices, one in each of the four operational HSE regions. Audits in food business operations were carried out to include an on-site 'reality verification' component to the audit as part of the confirmation of effective implementation of official controls at local level. In general, a structured approach for the organisation of staff was observed within each of the PEHO offices for the performance of official controls and a local management procedure was in place, which detailed how responsibilities had been organised within the office, and specified the official control duties to be performed.

To illustrate the Environmental Health Service planning and prioritisation process, the *Environment Health Business Plan 2012* was provided to the audit team which outlined the minimum obligations to be met by the Environmental Health Service in 2012, including targets for the FSAI Service Contract delivery.

The audit team confirmed that the inspection frequencies to be performed in relation to Category 1 and 2 establishments were generally being met in accordance with the requirements set out in the FSAI's *Guidance Note No.1* and the *Environment Health Business Plan 2012*.

An effective system of official controls for both microbiological and chemical sampling was in place and was verified at both national and local level during the audit. The sampling plans within each of the offices were being reviewed regularly and were adaptable to changing resources, establishment profiles, in accordance with risk-based priorities.

In accordance with its contractual and legal requirements, the HSE Environmental Health Service is required to provide staff and resources at a level that will deliver the service outputs/activities defined in Schedule 2 of the FSAI Service Contract, and meet the operational requirements of the legislation to be complied with.

Both parties to the Service Contract accept that staffing levels over the period of this contract will decrease. In three offices visited, staff reductions were clearly evident and directly impacted on the performance of official controls. The Environmental Health Service was planning a reconfiguration process at the time of audit to redistribute current available staffing resources to match Environmental Health Service priorities, but this had not

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<sup>1</sup> Note: The process of risk classification of food establishments, i.e. in order to assign a risk category of 1 to 6 in accordance with the establishment's risk profile, is defined in the FSAI's *Guidance Note No. 1 (Rev2)*.

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been implemented at the time of the FSAI audit and consequently, the alignment/allocation of resources to meet priorities was not fully adequate. This was evidenced by the fact that certain PEHO offices were not capable of meeting certain minimum inspection targets, i.e. without additional resources, by comparison to other offices that could deliver these requirements.

The whole time equivalent figures for staff within each PEHO office were used to compare available resources present at local level, for the performance of official controls in each of the four Environmental Health Service regions audited. The combined environmental health officer (EHO) and senior environmental health officer (SEHO) whole time equivalents were calculated as a total figure within each individual PEHO office to capture the available resources present for the performance of official controls. A significant disparity exists at local level, when comparing the available resources, i.e. within PEHO offices, available across the regions and the official control targets to be delivered, in accordance with the requirements of FSAI *Guidance Note No.1* and the *Environment Health Business Plan 2012*.

For example, the minimum number of planned inspections to be carried out, i.e. per combined EHO/SEHO whole time equivalent, in the Dublin Mid-Leinster PEHO office is 174, which is almost double the inspection requirements to be met when compared to the figure of 89 planned inspections to be completed per whole time equivalent, for the West PEHO office.

As a result of staff resources not being distributed equitably, which directly impacts on targets and performance delivery at local level, a number of PEHO offices fell short of meeting the expected minimum inspection frequency targets to be delivered in accordance with FSAI *Guidance Note No.1* requirements. On a number of occasions, intervention from the Regional Chief Environmental Health Officer was observed in order to reprioritise and reallocate resources within the PEHO offices.

During the audit, certain shortfalls in inspection frequency targets to be delivered were observed in the PEHO offices audited. This was particularly the case in a number of PEHO offices for Category 3 classified establishments and, more frequently for all offices, for Category 4 and 5 food business operations. Consequently, the requirements of FSAI *Guidance Note No.1* and the *Environment Health Business Plan 2012* were not being met for these establishments, i.e. in relation to target inspection frequencies to be achieved.

Although variation was present in each of the four offices regarding the numbers and types of Category 2 establishments present, the audit team was satisfied that this was not due to an inconsistent application of *Guidance Note No.1* from the evidence provided.

To illustrate the Environmental Health Service planning and prioritisation process, the *Environment Health Business Plan 2012* was provided to the audit team which outlined the minimum obligations to be met by the Environmental Health Service in 2012, including targets for the FSAI Service Contract delivery.

Although many targets were being delivered in accordance with stated requirements in the *Environment Health Business Plan 2012*, in other cases observed, a number of the "Priority 1 – Corporate EH Service Priorities" for 2012, were clearly not met within the timeframes specified for service delivery. For example, the establishment of an internal audit unit in order to meet the requirements of article 4.6 of Regulation 882/2004 was not delivered within the 2012 timeframe. The failure to implement the internal audit function was identified by the FSAI audit team as a weakness in the HSE system of official controls and does not comply with either the requirements of Regulation (EC) No 882/2004 or the FSAI Service Contract.

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Consequently, the FSAI's audit team view was that certain minimum obligations to be met by the Environmental Health Service annually (as stated in the *Environment Health Business Plan 2012*), including targets for the FSAI service contract delivery, were also not being fully achieved in accordance with requirements.

Monitoring of targets against the *Environment Health Business Plan 2012* was being carried out at local and national level. Evidence of reviews of performance at local level, in order to determine the effectiveness of official controls conducted, was provided in three of the four PEHO offices visited. For one PEHO office, due to the lack of evidence of reviews, this process could not be considered as effective. Due to the variation in the review approach and process between certain PEHO offices visited, a standardised approach for conducting reviews could not be considered to be fully place within the Environmental Health Service. At national level, a review of effectiveness in the Environmental Health Service, although planned, could not be confirmed as being fully in place at the time of the FSAI audit.

In general, Environmental Health Service national protocols for the performance of official control activities were being followed within each of the PEHO offices visited subject to a number of exceptions identified. Inspections carried out in Category 2 premises were for the most part being followed up as per *Guidance Note No. 1*. In the files audited, the food business operators in general, received a report after inspections in line with requirements. However, for a number of files reviewed, verification of close-out had not always been documented/confirmed during subsequent inspections, and/or timeframes for remedying certain deficiencies had not always been specified.

Communication from national meetings regarding enforcement consistency, supervisory issues and relevant topics is communicated to Environmental Health Service staff within the four offices. However, in two of the four offices, there was a lack of evidence of in-house review/discussion of relevant issues in order to demonstrate effective co-ordination and communication at local level.

Staff interviewed in each of the four PEHO offices were knowledgeable of the relevant national and EU legislation requirements and also with *Guidance Note No. 1* and Environmental Health Service protocols.

Individual reports of preliminary audit findings for each PEHO office audited were issued following the FSAI audit, which also detailed the corrective actions to be addressed by the Environmental Health Service. These have also been summarised again in this report in order to reflect a national audit perspective and to ensure that, where relevant, these findings are addressed across all Environmental Health Service regions.

Certain additional findings identified by the FSAI in this report have also been raised with Environmental Health Service management already as part of the delivery of the Service Contract requirements. Consequently, proposed corrective actions and follow-up should reflect their current disposition and status.

[Click on the Corrective Action Plan for more information.](#)

### **3. INTRODUCTION**

The FSAI is responsible for the enforcement of all food legislation in Ireland. The FSAI carries out this enforcement function through service contracts with official agencies. These service contracts outline an agreed level and standard of food safety activity that the official agencies perform as agents of the FSAI. The HSE has entered into a service contract with the FSAI and is responsible for the implementation and enforcement of national and EU legislation as it applies to food businesses under its supervision. It is a requirement of the service contract and food legislation that the HSE ensures that official controls are carried out regularly, on a risk basis, and with appropriate frequency.

As part of its legal mandate, and in accordance with Schedule 5 of the Service Contract, the FSAI is required to verify that the system of official controls is working effectively. This audit was carried out for the purposes of assessing the official controls carried out by the HSE in Category 2 classified food business operations. Compliance by the HSE with relevant food legislation, adherence to the terms and requirements of the FSAI Service Contract, as well as conformance with relevant documented procedures, were assessed.

This report describes the audit objective, scope, methodology and the findings of the audit. The information in this report relates solely to the areas audited and is not necessarily reflective of the situation in other areas.

#### **3.1 Audit Objective**

The primary objective of this audit was to verify the performance of official controls in Category 2 classified food business operations. The audit also focussed on the management and delivery of official controls within the Environmental Health Service at both national and local levels in order to confirm compliance with the requirements of the FSAI Service Contract, Regulation (EC) No 882/2004 and the Multi-annual National Control Plan.

#### **3.2 Audit Scope**

FSAI audits of official controls involve verifying compliance by official agencies with relevant legislation, adherence to the FSAI Service Contract requirements, relevant documented procedures and Multi-annual National Control Plan. Food business operations classified as Category 2 according to the criteria set out in FSAI *Guidance Note No.1* were selected to verify the performance of HSE official controls.

The audit commenced with an opening meeting with representatives from HSE Environmental Health Service at national level, and was followed by audits of four environmental health offices. On-site audit activities were conducted at Category 2 classified food business operator establishments, as part of the verification of HSE official control activities.

### **3.3 Audit Criteria and Reference Documents**

During the audit, compliance with the audit criteria was assessed, which included:

- [Regulation \(EC\) No 882/2004](#) on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended
- [Regulation \(EC\) No 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- [Regulation \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended
- [Food Safety Authority of Ireland Act, 1998](#) (S.I. No 29 of 1998), as amended
- Service Contract between the FSAI and the HSE
- The Multi-annual National Control Plan for Ireland, 2012-2016
- Health Service Executive Business/Service Plans and data supplied to the FSAI
- Environmental Health Service National Protocols
- FSAI Guidance Notes

### **3.4 Audit Methodology**

This audit of official controls was undertaken using documented procedures which are included in the FSAI Quality Management System, namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI audit obligations, defined in Schedule 5 of the Service Contract between the FSAI and the HSE, and are in accordance with the requirements of Regulation (EC) No 882/2004, Commission Decision 2006/677/EC and the FSAI Act.

A pre-audit questionnaire was forwarded to the four environmental health service offices visited. The purpose of the pre-audit questionnaire was to collate and confirm information regarding official controls and Category 2 food establishments in each of the areas audited.

An evaluation plan was developed together with audit explanation documents, which provided a detailed overview of the audit including the audit scope, objectives, criteria and team. The evaluation plan also included a proposed itinerary for on-site activity.

The first part of the audit at national level, involved an assessment of the planning, coordination, delivery of official controls for the Environmental Health Service countrywide, and discussions/interviews were carried out with representatives of the Environmental Health Service national management team, i.e. RCEHOs.

The second part of the audit involved visits to four selected PEHO offices within each of the Environmental Health Service national regions. This involved discussions/interviews with the PEHO and Environmental Health Service staff within the local office, relating to the performance and delivery of Environmental Health Service officials. A review of the information provided as part of the pre-audit questionnaire, as well as an audit of paperwork associated with official controls, was carried out by the FSAI audit team. The evidence examined as part of the audit in the PEHO office included:

- Baseline targets for the performance of official controls and their returns forwarded to the RCEHO
- Risk categorisation of Category 2 establishments in accordance with *Guidance Note No. 1*
- Inspection reports for official control inspections and cross checking against local IT system databases
- Communications, reports and letters to food business operators
- Records of supervisory activities and training carried out by the PEHO and SEHO

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As part of the audit conducted at local level, visits to Category 2 classified food business operations were also performed. This on-site component verified the delivery and effectiveness of official control activities being carried out, as well as an audit of the establishments, to determine their compliance with food legislation.

A closing meeting was held at the end of the audit in each region, in order to outline the main findings. The findings were discussed and each PEHO and his/her staff were given the opportunity to provide clarification and/or additional information. Findings relating to establishments audited were issued to the individual Environmental Health Service regions after the audit for follow-up with the food business operator.

A final closing meeting was held with the Environmental Health Service national management team at which the findings were delivered to the four RCEHOs.

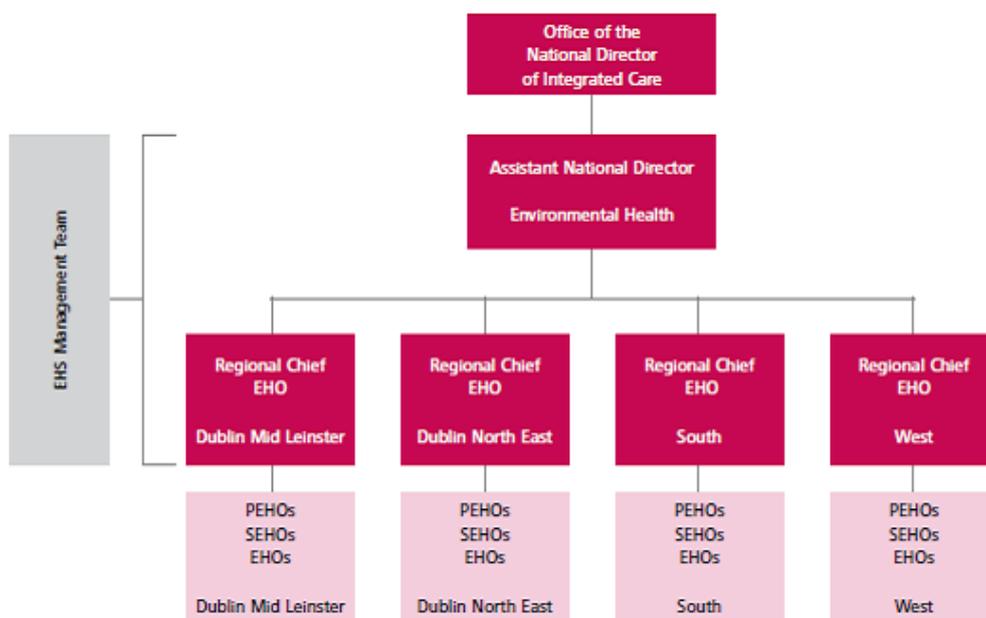
## 4. AUDIT FINDINGS - OFFICIAL CONTROLS PERFORMED IN ACCORDANCE WITH REGULATION (EC) No 882/2004

### 4.1 Organisation and Structure of Environmental Health Service Official Control Activities

Article 4 of Regulation (EC) No 882/2004 states that “Member States are required to designate the competent authorities (CAs) responsible for the performance of the official controls as set out in the Regulation”.

The Environmental Health Service provides a range of food safety/food control services in accordance with its Service Contract with the FSAI. These services include inspection of relevant food businesses together with food sampling to ensure compliance with food law, the management of food alerts and outbreaks, and a range of compliance building/education measures. The Environmental Health Service operates as a national service in the HSE. Currently, the Environmental Health Service is divided into four operational regions (see Figure 1 for details – source ([Multi-annual National Control Plan 2012-2016](#))): Dublin North-East, South, West and Dublin Mid-Leinster.

Figure 1: Organisational Structure of Environmental Health Service



The audit team confirmed that the structure and organisation of Environmental Health Service services and activities were in accordance with the description provided in the *Multi-annual National Control Plan 2012-2016*.

The Environmental Health Service is managed nationally by the Assistant National Director for Environmental Health and Emergency Management and four RCEHOs. The audit team was informed that the national management team was responsible within the Environmental Health Service for implementing policy, setting the control framework for the service nationally via development of the National Service Plan, agreeing budgets/staffing levels within environmental health offices and for the monitoring and control of performance.

At local level, a PEHO manages Environmental Health Service operational activities within an environmental health office and reports directly to the designated RCEHO for that region. The audit team confirmed that a local management procedure was in place within each of the four PEHO offices visited, detailing how responsibilities had been allocated and organised within the office, and specified the official control duties to be performed.

Within the local offices visited, SEHOs reported directly to the PEHO and typically, were also involved in managing activities with a team of EHOs. SEHOs had also been assigned additional specific duties within the local office and accompanied EHOs on certain inspections. EHOs were responsible for performing the routine official control activities such as inspections and sampling activities and had also been assigned certain other specific responsibilities within the environmental health office, in addition to the supervision of food business operator establishments (see Section 4.3 in relation to the reduction of staff resources in the Environmental Health Service and their allocation).

## **4.2 Coordination of Environmental Health Service official control activities**

In accordance with Article 4.5 of Regulation (EC) No 882/2004, when within a competent authority, more than one unit carries out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

The audit team confirmed that the national management team met to discuss priorities within the Environmental Health Service and evidence of meetings was provided for 2012. In general, the audit team observed active communication between the RCEHOs/national management team and the PEHOs in the four regional offices visited. Evidence of the minutes of regional meetings between the RCEHO and the PEHOs within their region were also provided and the audit team was informed that these meetings typically take place on a quarterly basis.

At local level, the audit team confirmed that regular meetings were taking place between the PEHO and with staff in each of the four environmental health offices visited. Close liaison between the PEHO and the SEHOs was evident in each office and typically, SEHOs were responsible for managing activities with a team of EHOs and for reporting directly to the PEHO on official control performance outputs from their group. In three of the four offices, the PEHO also met formally on an individual basis with EHOs to review performance and to provide direct feedback to EHOs involved.

In most cases observed within the environmental health offices visited, co-ordination of official controls and updates on official control activities are provided to staff via team meetings. The audit team was provided with agendas and examples of meetings that had taken place in 2012 and where evidence of the dissemination and communication of the above information was taking place. In one environmental health office, the RCEHO also attended a number of staff meetings in 2012.

### **4.3 Provision of Environmental Health Service Resources for the Performance of Official Controls**

Article 4 of Regulation (EC) No 882/2004 and Schedule 3 of the FSAI Service Contract requires the competent authority to fulfil a number of operational criteria, which includes:

- Provision of a sufficient number of suitably qualified and experienced staff (see Section 4.9 on training of Environmental Health Service personnel)
- Provision of adequate facilities and equipment in order to carry out duties properly

The audit team confirmed that adequate facilities and equipment were present in each of the four environmental health offices visited (in one case however, certain equipment had not been fully calibrated in accordance with Environmental Health Service requirements – see Section 4.7 on following of Environmental Health Service national protocols).

The HSE must provide staff and resources at a level that will deliver the service outputs/activities defined in Schedule 2 of the Service Contract and meet the operational requirements of the legislation to be complied with.

The audit team was informed at national level that staff reductions and restrictions on filling posts at all levels within the HSE Environmental Health Service (without the possibility of filling posts) posed significant challenges for the organisation in fulfilling all its legal and contractual obligations. At the time of the audit, the service was undergoing a reconfiguration process designed to redistribute current available staffing resources to match Environmental Health Service priorities. The audit team was informed that this was due to be completed later in 2013.

The audit team confirmed that in addition to the general reductions in staff within the service, other factors such as various types of staff leave, e.g. maternity, long-term sick leave, etc... without the possibility of replacement cover impacted on available resources for service delivery. Additionally, the involvement of environmental health staff in certain Environmental Health Service projects such as the development on Environmental Health Information System (EHIS) project, also directly affected available resources within the environmental health offices for food control.

In each of the environmental health offices visited, the PEHO was responsible for the organisation of staff cover and allocation of duties whilst leave arrangements were being signed off by the RCEHO at national level.

Table 1 provides an overview of the staffing complement within environmental health office visited. Staffing levels were provided in the pre-audit questionnaire returned by each environmental health office audited, i.e. as of the 31st September 2012. In three of the four offices visited, a noticeable reduction in staffing levels had occurred since 2011.

**Table 1: Overview of Resources in Local PEHO Offices**

| Staffing levels<br>(31 <sup>st</sup> Sept 2012)                          | Dublin<br>North East | Dublin Mid-<br>Leinster | South     | West          |
|--|----------------------|-------------------------|-----------|---------------|
| PEHO   | 1 (0.8*)             | 1 (0.8*)                | 1 (0.75*) | 1 (0.6*)      |
| SEHO   | 3 (2.5*)             | 4 (1.85*)               | 2 (1.15*) | 2.25 (1.85*)  |
| EHO  | 5 (4.8*)             | 6 (3.8*)                | 3 (2.2*)  | 7.75 (5.8*)   |
| Administrative   | 3 (0.3*)             | 2 (1.4*)                | 3 (0.8*)  | 3.1 (2.1*)    |
| Total  | 12 (8.4*)            | 13 (7.85*)              | 9 (4.9*)  | 14.1 (10.35*) |
| Total Combined SEHO/EHO whole time<br>equivalent* per PEHO office (2012) | 7.3                  | 5.65                    | 3.35      | 7.65          |

\*Note: Whole time equivalent involved in food control activities

- In the Dublin Mid-Leinster region, the total whole time equivalent in the PEHO office for food control was 7.85 in September 2012 compared with 8.45 in September 2011. The office was down 2 EHO posts since 2011.
- In the South region, the total whole time equivalent in the PEHO office for food control was 4.9 in September 2012 compared with 5.3 in September 2011.

For both of these offices, communications took place in 2012 between the PEHO and the RCEHO outlining the fact that they would not be able to deliver inspection frequencies in line with *Guidance Note No. 1* and/or the environmental health baseline targets agreed in Quarter 1 2012 in order to meet Environmental Health Service national priorities.

- In the Dublin North-East region, the total whole time equivalent in the PEHO office for food control was 8.4 in September 2012 compared with 10.4 in September 2011. The environmental health office was down 2 EHO posts since 2011. At the time of the audit, 1 EHO was on maternity leave while another had been allocated to national Environmental Health Service duties as part of the EHIS project.

Consequently, in three offices visited, staff reductions were clearly evident and directly impacted on available resources for the performance of official controls. By comparison, for another PEHO office in the Environmental Health Service West region, staffing reductions had not occurred to the same degree.

- For the Environmental Health Service in the West region, the total whole time equivalent in the PEHO office for food control was 10.35 in September 2012 and was only slightly down when compared with a whole time equivalent of 10.45 in September 2011.

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The total number of Category 1–Category 5 (i.e. C1 – C5) establishments in each of the four PEHO offices visited is illustrated in Table 2<sup>2</sup>.

**Table 2: Total C1 - C5 Food Business Operator Establishments in the Four PEHO Offices Visited**

| <b>Guidance Note No. 1 Risk Classified Establishments/<br/>Environmental Health Office<br/>(Quarter 1 2012)*</b> | <b>Dublin<br/>North East</b> | <b>Dublin Mid-<br/>Leinster</b> | <b>South</b> | <b>West</b> |
|--|------------------------------|---------------------------------|--------------|-------------|
| Category 1   | 7                            | 12                              | 1            | 6           |
| Category 2   | 63                           | 133                             | 75           | 92          |
| Category 3   | 471                          | 805                             | 264          | 549         |
| Category 4   | 416                          | 439                             | 440          | 228         |
| Category 5   | 336                          | 226                             | 241          | 302         |
| Total C1 – C5  | 1,293                        | 1,615                           | 1,021        | 1,177       |

In general, the audit team observed that a consistent application of the guidance note regarding risk profiling of food business operator activities and operations had been carried out in each of the four PEHO offices visited from the evidence provided during the audit (see also Section 4.4 of this report). The figures in Table 2 clearly indicate a much higher total number of establishments in the Dublin Mid-Leinster PEHO office when compared to other offices

The whole time equivalent figures for staff within each PEHO office were used to compare available resources present at local level for the performance of official controls in each of the four Environmental Health Service regions audited. The combined EHO and SEHO whole time equivalents were calculated as a total figure within each individual PEHO office, i.e. as per Table 1, in order to capture the available resources present to meet the expected official controls requirements to be delivered in Table 2.

<sup>2</sup> Note: The process of risk classification of food establishments, i.e. in order to assign a risk category in accordance with the establishment's risk profile, is defined in FSAI *Guidance Note No. 1 (Rev 2)*.

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Table 3 provides details of the approximate minimum inspection frequency targets to be achieved in 2012 when making a comparison between available resources in each of four PEHO offices and the inspection requirements to be delivered in accordance with their risk categorisation and FSAI *Guidance Note No. 1* requirements.

**Table 3: No. of Planned Inspections per EHO/SEHO Whole Time Equivalent at Minimum Inspection Frequency**

| Number of Planned Inspections for C1- C5 Establishments at the minimum frequency ( <i>Guidance Note No. 1</i> ) | Dublin North East | Dublin Mid Leinster | South | West |
|---|-------------------|---------------------|-------|------|
| Category 1  | 14                | 24                  | 2     | 12   |
| Category 2  | 126               | 266                 | 150   | 184  |
| Category 3  | 311               | 531                 | 174   | 362  |
| Category 4  | 208               | 220                 | 220   | 114  |
| Category 5  | 111               | 531                 | 174   | 362  |
| Total C1 – C5   | 707               | 982                 | 551   | 680  |
| Total Planned Inspections per SEHO/EHO whole time equivalent** for C1 –C5 establishments                        | 97                | 174                 | 164   | 89   |

\* Source: C1 – C5 establishments taken from baseline figures, *Environmental Health Business Plan 2012*.

\*\*Source: Total combined SEHO/EHO whole time equivalent\* per PEHO office (2012) taken from Table 1

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 *Guidance Note No. 1* and the *Environment Health Business Plan 2012*.

For example, the minimum number of planned inspections to be carried out, i.e. per combined EHO/SEHO whole time equivalent, in the Dublin Mid-Leinster PEHO office is 174, which is almost double the inspection requirements to be met, when compared to the figure of 89 planned inspections to be performed per whole time equivalent, for the West PEHO office.

Additionally:

- The combined higher risk category total present, e.g. Category 1, 2 and 3 establishments, for the Dublin Mid-Leinster PEHO office, relative to existing resources present, placed significantly greater inspection demands on the available resources within this office. In the case of Category 3 establishments, the audit team was informed that inspection targets would not be met for 2012 without the additional provision of resources

- In relation to the South PEHO office, the minimum number of planned inspections per combined EHO/SEHO whole time equivalent was 164 compared to the Dublin North-East and West region PEHO offices, which were 97 and 89 respectively. This clearly demonstrated a significant variation in the availability of resources within the PEHO office and their alignment to meet inspection frequency demands. Due to an already existing low staffing complement in 2011 within the South PEHO office, the audit team noted that the further staff reductions in 2012 had a significant impact on this particular office for the delivery of official controls

In both the case of the Dublin Mid-Leinster and South region PEHO offices, communications took place between the PEHO the relevant RCEHO regarding their difficulties in meeting the *Environment Health Business Plan* inspection targets for 2012. In the West region by comparison, where the combined EHO/SEHO whole time equivalent per establishment was the highest of the four regions audited, the audit team was informed that the PEHO was achieving their targets in line with *Guidance Note No. 1* for all Category 1, 2 and 3 establishments. Quarterly return results were provided as supporting evidence.

Also relevant at the time of the audit, from an inspection viewpoint, is the fact that within each of the four offices visited, target frequencies for 2012 for all Category 1 to 5 establishments had been set at the standard frequency. The figures illustrated in this report account for deliverables to be met within the four PEHO offices at the minimum frequency. If applied at the standard frequency agreed for 2012, the inspection targets and variation between PEHO offices essentially doubles. These additional factors however, are not tabulated within this report, as they only serve to further reinforce variation in resources between offices in order to meet inspection demands and these trends are already illustrated at the minimum frequency inspection level (see Table 3).

In relation to staffing levels within the Environmental Health Service for 2013, communications were provided to the audit team by the Environmental Health Service national management team highlighting further expected reductions in available resources nationally, where PEHOs at local level were requested to anticipate a further 6.5% reduction in the environmental health whole time equivalents within the Environmental Health Service. PEHOs were asked to factor this into their planning and prioritisation of Environmental Health Service activities within their office for the forthcoming year.

The audit team confirmed that there were no unassigned food business operators for Category 1, 2 and 3 establishments within the environmental health offices visited, where due to reallocation of duties amongst EHOs/SEHOs by the PEHO, (and also on occasion with RCEHO involvement), food business operator establishments had been redistributed amongst existing staff.

#### 4.4 Risk-based Planning and Prioritisation of Official Controls within the Environmental Health Service

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency.

An overview of the environmental health planning and prioritisation process for service delivery at national level was provided by the Environmental Health Service national management team during the opening meeting of the FSAI audit. These included responsibilities and associated deliverables to be achieved for the Department of Health, the HSE and for the FSAI, as part of the Service Contract.

As evidence of the planning and prioritisation process, the national management team provided the FSAI audit team with the *Environmental Health Business Plan 2012* and details from the draft National Service Plan for 2013.

An extract from the *Environmental Health Business Plan 2012* illustrates the hierarchical planning and prioritisation process:

*“The Environmental Health Business Plan links into the National Service Plan (NSP) for 2012 and the National HSE Corporate Plan for 2011 – 2014. It reflects the HSE’s minimum obligations as a statutory enforcement authority and takes into account the obligations of the Environmental Health Service under the agreed HSE/FSAI Service Contract”.*

*“The EH BP identifies the functions of the Environmental Health Service in order of priority which must be delivered in 2012”.*

In relation to the prioritisation of Environmental Health Service activities for performance of official food control activities for 2012, these were being planned/scheduled in order to meet the requirements of the *Environmental Health Business Plan 2012*. The priorities in the business plan are organised in order to meet the requirements of the FSAI Service Contract and include targets for inspections, sampling activities, reacting to food alerts, complaints, etc. The *Environmental Health Business Plan 2012* specified minimum activity levels/outputs for inspection delivery in local PEHO offices for all Category 1 to 5 food business operator establishments, which was set at standard inspection frequency. The performance expected for each PEHO office was 100% delivery in accordance with the standard inspection requirements for the FSAI’s *Guidance Note No.1*.

Delivery of the *Environmental Health Business Plan 2012* requirements were being assessed by the national management team against ‘baseline targets’ to be achieved by the Environmental Health Service nationally, which had been requested from the local PEHO offices in Quarter 1 2012.

The audit team confirmed that several targets to be met, as specified in the *Environmental Health Business Plan 2012*, were not achieved as part of the Environmental Health Service approach to deliver its minimum obligations, which also included aspects directly applicable to the FSAI Service Contract (see Section 4.10).

The audit team observed that for 2013, the target frequency for inspections to be carried out had also been changed to the minimum inspection frequency, which was outlined by the Environmental Health Service national management team at the closing meeting for the audit and in the draft *Environmental Health Business Plan 2013* provided.

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The audit team confirmed that in each of the four PEHO offices, official control sampling activities were being performed in accordance with the risk-based microbiological sampling document (dated June 2012) and the chemical sampling plans for 2012. An effective system was in place at both national and local levels. The sampling plans within each of the offices were being reviewed regularly and were adaptable to changing resources, establishment profiles, in accordance with risk-based priorities.

In each of the PEHO offices visited, FSAI *Guidance Note No. 1* was being used to risk categorise food businesses in order to determine the frequency of planned inspections. The audit team confirmed that, for the Category 2 establishments audited within each of the four offices visited, the associated factors in order to determine risk categorisation had been taken into account, which included history of compliance, level of risk, volume of production, type of products handled and food operation activities.

A priority action list<sup>3</sup> was also in place in all of the Environmental Health Service offices audited and was being actively reviewed, which was also in accordance with *Guidance Note No. 1* requirements. Differences were observed in relation to the types and numbers of Category 2 establishments within the four regions audited (see Table 4). The audit team verified that all Category 2 classified establishments (from the sample of files reviewed) were registered under Regulation (EC) No 852/2004 or equivalent and were risk categorised appropriately.

The audit team observed that no establishments which required approval under Regulation (EC) No 853/2004 fell within the scope of the audit. They had all been classified as Category 1 establishments as per FSAI *Guidance Note No. 1*.

During the audit of the Environmental Health Service South region PEHO office, it was established that certain premises, e.g. bakeries (previously classified as Category 2) had been re-categorised as lower risk following review of their risk profile prior to the FSAI audit. As a result, no Category 2 manufacturing establishments were present within the Environmental Health Service South region PEHO office. The audit team was satisfied with the rationale and evidence provided during the audit for the change of food business operator categorisation.

**Table 4: Category 2\* Food Business Operator Establishments falling within the Scope of the FSAI Audit**

| Category 2 Establishments per Environmental Health Office | Dublin North East | Dublin Mid-Leinster | South | West |
|---|-------------------|---------------------|-------|------|
| Hotels  | 8                 | 8                   | 11    | 4    |
| Restaurants   | 0                 | 21                  | 3     | 5    |
| Manufacturers   | 2                 | 7                   | 0     | 8    |
| Total   | 10                | 36                  | 14    | 17   |

\* Source: FSAI Pre-Audit Questionnaire completed by environmental health offices 2012

<sup>3</sup> A food business is placed on a priority action list if an EHO has particular food safety concerns, where the last inspection outcome was very unsatisfactory or if enforcement action is current/required.

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Although the audit team was in general, satisfied with the risk profiling of establishments within the four offices, evidence gathered during the course of the audit demonstrated that inconsistencies had been identified by the Environmental Health Service themselves where variation in the application of *Guidance Note No. 1* had been found. The audit team was satisfied that these inconsistencies were being addressed by the Environmental Health Service at national level. The FSAI audit team was informed by the national management team that a SEHO had been appointed to review risk categorisation and profiling of food establishments in PEHO offices nationally, in order to ensure a more consistent application of *Guidance Note No. 1*.

The audit team confirmed that for Category 1 and 2 establishments (which are the higher risk food business operations) inspection targets were in general, being achieved and/or managed in accordance with requirements within the PEHO office. This also on occasion involved intervention by the RCEHO in conjunction with the PEHO.

For example, in one PEHO office, intervention by the RCEHO resulted in the prioritisation for inspection of Category 1 and 2 establishments which had not been inspected in the last twelve months and were either unassigned or not scheduled to be inspected in 2012 due to resourcing issues.

However, at the time of the FSAI audit, in two of the four PEHO offices, not all Category 3 risk classified establishments were being inspected in accordance with the inspection target frequencies to be achieved as per the FSAI's *Guidance Note No. 1* and also with the *Environmental Health Business Plan 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 (see Section 4.3). This inability to meet the required targets had also been communicated to the national management team by all four PEHO offices via the baseline target figures submitted by the Environmental Health Service offices in Quarter 1 2012.

As a result all premises were not being inspected in accordance with the standard or minimum frequencies as required by FSAI *Guidance Note No. 1*. In certain cases, planned activities that had been committed to by the PEHO offices, as part of the Environmental Health Service baseline targets agreed with the national management team in Quarter 1 2012 were not being achieved, which was not fully in accordance with the requirements of the *Environmental Health Business Plan 2012*.

#### **4.5 Environmental Health Service Participation on Working Groups/Committees and Information Dissemination**

In accordance with the FSAI Service Contract with the HSE, the Environmental Health Service was participating in and contributing to relevant working groups and committees and evidence was provided that the outputs from these were being communicated to the national management team and to staff within the Environmental Health Service. The national management team had been involved in agreeing the terms of reference and allocating the lead representative to attend on behalf of the Environmental Health Service.

These working groups/committees included:

- Service Contract Committee on Enforcement Consistency
- Service Contract Committee on Food Legislation
- Cross Agency Supervisory Issues Group
- Service Contract Committee on Microbiological Sampling

The audit team reviewed communications from a number of the working groups/committees in order to confirm communication of relevant outputs/action points to the national management team and to track the dissemination of this information to staff at local level.

Communications from national meetings regarding enforcement consistency, supervisory issues and relevant topics were verified as taking place to Environmental Health Service staff within the four PEHO offices audited. However, in two of the four offices, there was no evidence of in-house review/discussion of these communications being recorded at section/team meetings in order to demonstrate effective coordination and communication of relevant issues and topics and the cascade of this information to local level.

#### **4.6 Registration/Approval of Food Business Operator Establishments**

In accordance with Schedule 4 of the FSAI Service Contract, the official agency is required to maintain an up-to-date national list of all food establishments which are under HSE supervision. This list must record the registration and approval status of each establishment in accordance with the requirements of Article 31 of Regulation (EC) No 882/2004. The data collected are to be maintained and all records are to be kept up-to-date.

During a review of the food business operator establishments, two lists had been provided to the FSAI by the Environmental Health Service. The audit team noted that for several Category 2 classified, 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. The audit team was informed that this was due to inaccuracies in the current lists which would be corrected when the new EHIS system was in place in May 2013. Consequently, the lists provided could not be considered as entirely meeting the requirements Regulation 882/2004 and the FSAI Service Contract. The audit team confirmed that for the Category 2 establishments selected within the Environmental Health Service offices visited, these had been registered in accordance with legislative and administrative requirements. The audit team confirmed that no 853/2004 approved establishments came within the scope of the audit (see Section 4.4).

At local level, the audit team confirmed that premises had been given a unique reference number and were present on the local IT management system for the office. Records of registration were also on file for the establishments reviewed and were in general accordance with the requirements of Environmental Health Service Protocol 1 – *Notification for Registration of Food Business Operator Establishment (Nov. 2011)*.

## **4.7 Documented Procedures**

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

In addition to national protocols, a number of local procedures were in operation within the PEHO offices visited:

- An audit trail/record for the documenting of file reviews was being used by one PEHO
- A local management procedure was in place in each of the four PEHO offices for the delegation of responsibilities and for the specification of tasks
- Official control sampling activities were being carried out in each of the four PEHO offices in accordance with the risk based microbiological sampling document (June 2012) and the chemical sampling plans for 2012

The sampling plans were being reviewed regularly and were adaptable to changing resources and establishment profiles, in accordance with risk-based priorities. Although Environmental Health Service protocols were generally being adhered to, certain documented procedures/protocols were however, not being fully complied with in a number of cases including:

- The master/reference temperature probe in West region PEHO office, which is used for internally calibrating other probes within the office, was out of calibration. Consequently, the requirements of Environmental Health Service Protocol No. 39 (Section 6.2.1) were not being fully adhered to. Following the identification of this finding, the PEHO office carried out a risk assessment of this finding and was confident that it had not impacted on previous enforcement actions taken by the office
- In the South and Dublin Mid-Leinster region PEHO offices, the calibration logs for probes used as part of official controls checks were not being fully maintained in accordance with Environmental Health Service Protocol No. 39 and the calibration status of certain probes was unclear on the day of the audit

In general, Category 2 food business operator establishments had been risk categorised in accordance with *Guidance Note No. 1* requirements. Inspections were planned in accordance with *Guidance Note No. 1*. However, certain target frequencies for inspections were not fully met (see Section 4.7) which was not fully in accordance with requirements to be met.

## **4.8 Reports to Food Business Operators and Follow-up and Close-out of Non-compliances**

Article 9 of Regulation (EC) No 882/2004 requires competent authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned. The competent authority shall provide the food business operator with a copy of the report on official controls carried out, at least in case of non-compliance.

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies a non-compliance, it shall ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record of non-compliance.

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Copies of inspection reports were available for all establishments audited. The essential official control information is recorded in the local Environmental Health Service database. The legislation requires inspection reports to be issued to the food business operator when non-compliances are found. In the files audited in the four PEHO offices, the food business operators in general, received a report after inspections in line with the FSAI's *Guidance Note No.1* and Environmental Health Service *Protocol No. 3 'Inspection of a Food Business'* requirements.

The detail of the information in the reports to food business operators can vary. In some offices, non-compliances only were being reported, while in others a detailed overview of all of the findings of the inspection, both positive and negative are recorded. Different systems were in place in the four areas audited to record the close-out of non-compliances at the next inspection.

Inspections carried out in Category 2 establishments were as a general rule, being followed up in accordance with the requirements of the FSAI's *Guidance Note No.1*, Regulation 882/2004 and Environmental Health Service protocols, with the exception of certain deficiencies, detailed below. For example:

- In the Dublin North East region PEHO office, for two files reviewed reports were not issued fully in line with documented procedures and in accordance with Article 9 of Regulation (EC) No 882/2004. For the other files reviewed reports had in general been issued in line with requirements
- For the Dublin Mid-Leinster PEHO office, timeframes for remedying corrective actions were generally included on the report to the food business operator, although a few exceptions were also observed. Findings from previous inspections were generally being assessed for their close-out at the next inspection, however on occasion, this was not always fully documented
- In the South PEHO office, findings from previous inspections were generally being assessed for their close-out at the next inspection, however on occasion this was not always documented on Environmental Health Service files. In general, reports to the food business operator included timeframes for implementing corrective action to remedy non-compliances identified; although in a number of cases for certain reports reviewed by the audit team, the timeframe was not specified
- In the West PEHO, office findings from previous inspections are generally assessed for their close-out at the next inspection, however for a number of files reviewed this was not fully documented. In some cases however, timeframes for remedying non-compliances identified during inspections, were not included in the reports to the food business operator

A priority action list was in place, in each of the PEHO offices visited and was being reviewed regularly at staff meetings and managed in line with Environmental Health Service protocols and *Guidance Note No. 1* requirements.

A complaints roster was in place in all four PEHO offices visited and was being well managed so as to ensure all complaints are closed out. When an EHO is on leave the roster is reorganised to ensure follow-up takes place.

## **4.9 Staff Performing Official Controls**

The official agency is required to ensure that staff performing official controls have received sufficient training for their area of competence.

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure staff performing official controls are suitably qualified and experienced staff; that appropriate and properly maintained facilities and equipment are available; and that staff performing controls are free of any conflict of interest.

Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff receive appropriate training and are kept up-to-date in their competencies.

Staff interviewed in each of the four PEHO offices were in general, knowledgeable of the relevant national and EU legislation requirements and also with *Guidance Note No.1* and Environmental Health Service protocols.

Historically, the Environmental Health Service arranged training locally and between a number of PEHO areas. Evidence of training for environmental health staff carried out in each of the four PEHO offices was provided for 2010-2012. A training needs assessment has been completed for Environmental Health Service staff and this has been returned for inclusion in the national training plan 2012-2013. A training log was in place for each EHO.

A national training plan was developed in 2012 but had yet to be fully implemented at the time of the FSAI audit.

## **4.10 Performance and Review of Environmental Health Service Official Control Activities**

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

Article 4(6) of the Regulation requires competent authorities to carry out internal audits or have external audits carried out.

Article 8(3) requires competent authorities to have procedures in place to verify the effectiveness of official controls and to ensure corrective action is taken when needed and to update documentation as appropriate.

Monitoring of targets against the *Environmental Health Business Plan 2012* was being carried out by the PEHO/SEHOs within the environmental health offices visited. This takes place principally via the compilation of quarterly returns for the Environmental Health Service National Office which also provides results indicating whether official controls are being carried out in line with the targets of the *Environmental Health Business Plan 2012* and the associated baseline targets to be delivered.

RCEHO intervention was also observed when communications from local level indicated that not all environmental health baseline and quarterly returns targets would be met. In a number of cases, this resulted in reprioritisation of duties and official control activities within the environmental health offices to focus on higher risk establishments and to ensure inspections were carried out.

In general, target delivery is also discussed at environmental health staff meetings and can also take place individually between the PEHO/SEHO and EHOs within environmental health offices.

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Verification and review of official controls was generally being organised at local level by the PEHO and/or in combination with SEHOs. Different arrangements were observed in place in the different environmental health offices audited, including:

- File reviews, which were conducted periodically by PEHOs or SEHOs in certain of the offices visited, to ensure the consistency and quality of inspections, inspection targets were being met and inspections carried out, reported on and in line with legislative requirements
- Regular staff and management meetings held to discuss enforcement issues and inspection activities.
- Joint inspections, may also take place where SEHO(s) accompany EHOs, for difficult and enforcement inspections<sup>4</sup>, for large manufacturers, food poisoning investigations, and/or on night inspections
- Active review of the priority action list was observed within all offices visited

Evidence of reviews to determine the effectiveness of official controls was provided in three of the four PEHO office visited. For one office however (Dublin Mid-Leinster region), the audit team was informed that an informal approach to assess effectiveness was in place within this office and that a year-end review of the performance of official controls, was scheduled to take place before the end of 2012. At 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 (EC) No 882/2004. Consequently, a standardised approach for conducting reviews within PEHO offices nationally could not be considered to be fully in place.

At national level, the audit team was informed that a formal year-end review of performance of official controls within the Environmental Health Service was scheduled to take place in January 2013. Consequently, a review of the effectiveness of Environmental Health Service official controls at national level, although planned, could not be considered to have taken place at the time of the FSAI audit. A broad outline of the elements to be included in the review process was however, provided to the audit team.

In relation to the prioritisation of Environmental Health Service activities, these are specified in the *Environmental Health Business Plan 2012*, which specifies the Environmental Health Service approach to deliver its corporate and minimum statutory obligations and includes aspects directly applicable to the FSAI Service Contract. These included targets for inspections, sampling activities, reacting to food alerts, complaints, etc.

The audit team confirmed that a number of the Priority 1 – Corporate Environmental Health Service Priorities were not fully met in 2012, which also relate directly to the delivery of the FSAI's Service Contract requirements.

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<sup>4</sup> In accordance with the FSAI's *Guidance Note No. 1*, an enforcement inspection is conducted to ensure that identified significant or serious non-compliances are remedied by the food business operator.

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For example:

- Implementation of Reconfiguration of Environmental Health Service activities and resources: The national environmental health resources and service delivery model was not implemented by 31<sup>st</sup> of December 2012 (the draft Business Plan for 2013 provided to the audit team for 2013 includes a revised target completion date for June 2013). Additionally, the audit team view is that the disparity observed between resources in the PEHO offices audited and the official control activities to be met/delivered, clearly demonstrated that this process had not been implemented
- Establishment of Internal Audit Unit: The internal audit function to be set up by 31<sup>st</sup> of December 2012 had not been established at the time of the audit

Certain elements of the business plan were also considered as being implemented from the evidence provided to the audit team and in compliance with the FSAI service contract requirements such as:

- Implementation of the FSAI's *Guidance Note No. 1* (Requirement for each office to fully implement *Guidance Note No. 1*) - to be fully implemented by 31<sup>st</sup> December 2012. The audit team was satisfied that *Guidance Note No. 1* had been implemented and that the Environmental Health Service had embarked on a review process to improve the risk profiling of establishments in PEHO offices which was being managed at national level
- Implementation of National Protocols: All protocols to be implemented by local offices no later than March 2012. The audit team was satisfied that Environmental Health Service protocols relevant to the FSAI Service Contract were in general, being implemented nationally from the sample of PEHO offices visited during the FSAI audit

The audit team confirmed that a number of the *Priority 3, 4 and 5 – Corporate Environmental Health Service Priorities* were not fully met in 2012, which also relate directly to the delivery of FSAI Service Contract requirements.

The audit team was satisfied that “*Priority 1 – reactive statutory obligations and demand led activities*” were being met in relation to food alerts and complaints and that “*Operational proactive statutory obligations*” were achieved in relation to supervision of Category 1 and 2 establishments. However, this was not the case in relation to inspections of Category 3, 4 and 5 establishments.

- The *Environmental Health Business Plan 2012* specified minimum activity levels/outputs for inspection delivery, in local PEHO offices, for all Category 1 to 5 establishments, which was set at the standard inspection frequency. The performance expected for each PEHO office was 100% delivery in accordance with the standard inspection requirements for FSAI *Guidance Note No. 1*. The audit team was satisfied that Category 1 and 2 establishments were being inspected in accordance with *Guidance Note No. 1* requirements in relation to the four PEHO offices visited. The audit team however, confirmed shortfalls in delivery of inspection frequencies in each of the four PEHO offices for Category 4 and 5 establishments and for certain PEHO offices in relation to Category 3 food business operators, which did not meet the requirements of the *Environmental Health Business Plan 2012* or FSAI *Guidance Note No. 1* requirements.

The audit team was provided with evidence of a review of the consistency of enforcement within the Environmental Health Service, where efforts were being made by the national management team to promote a uniform approach in relation to the content and issuing of enforcement notices/orders nationally.

Additionally, details were provided of a desktop review of the consistency of application of *Guidance Note No. 1* in relation to risk profiling of food business operator establishments. The draft document (dated 12<sup>th</sup> October 2012) was provided to the audit team. The purpose of the audit/review was to identify any inconsistencies in the application of *Guidance Note No. 1* and the risk profiling methodology in use, draft any required additional guidance and make recommendations on amendments to *Guidance Note No. 1*.

The audit team also confirmed that reviews were taking place in relation to the Environmental Health National Sampling Working Group where evidence was provided for 2011 and 2012. The review document for 2012 was dated 23<sup>rd</sup> October 2012 and consequently, certain action points were also flagged to be completed by year end, where the audit team was informed a final status/disposition in terms of delivery would be determined.

At national level, a system of internal audits had not commenced in 2012. The national management team provided a broad outline of how this is to be organised. The audit team was informed however, that this was dependent on the reconfiguration process. Consequently, the audit team's view was that the Environmental Health Service was currently not complying with either the requirements of Article 4(6) of Regulation (EC) No 882/2004 and Section 1.20 of the Service Contract and this was identified as a weakness in the HSE system of official controls. FSAI audits do not substitute for the competent authority's responsibility to implement the requirements of Regulation (EC) No 882/2004.

## **5. FOOD BUSINESS OPERATOR CONTROLS PERFORMED IN ACCORDANCE WITH REGULATIONS 178/2002 AND 852/2004**

As part of the audit of the food business operations, the audit team assessed the performance of the controls put in place at the establishment in relation to the implementation of good hygiene practices and principles of HACCP (Hazard Analysis Critical Control Point) as part of the food business operator's food safety management system and whether these were being adequately maintained and were effective. An assessment was made under (a) Structure, Maintenance & Operational Hygiene (b) Food Safety Management System.

### **Structure, Maintenance & Operational Hygiene**

Articles 4(2) of Regulation (EC) No 852/2004 require food business operators to comply with general hygiene requirements as set out in Annex II of the Regulation. These provisions relate to cleaning and maintenance, layout, design, construction and size of food premises.

In general, the hygiene requirements relating to the design/layout, structure, equipment and facilities were being met in the establishments audited (subject to a number of deficiencies identified).

The audit team noted that in general, deficiencies were being identified and followed up by the HSE in the course of their inspections at food business operators' establishments.

In two establishments visited, there were on-going hygiene issues and some structural issues which had been identified in previous Environmental Health Service inspection reports and which had still yet to be fully closed out by the food business operator. At the closing meeting in both food business operator establishments with the Environmental Health Service, commitments were provided by the food business operator management to review and improve the identified deficiencies observed.

### **Food Safety Management System**

Article 5 of Regulation (EC) No 852/2004 requires food business operators to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. Regulation (EC) No 852/2004 allows the HACCP-based procedures to be implemented with flexibility so as to ensure that they can be applied in all situations.

In general, documented food safety management systems based on the principles of HACCP, including procedures and records, had been put in place by the food business operators at each of the establishments audited, in order to comply with the requirements of Article 5 of Regulation (EC) No 853/2004 and in most cases, these food safety management systems were being implemented in accordance with requirements, subject to a number of exceptions identified by the FSAI audit team. In three establishments, the food business operator's food safety management system was not entirely up-to-date/reflective of current operations.

- In three establishments there were shortcomings in relation to calibration of equipment.
- In the one establishment, the food safety management system was not sufficiently documented in relation to hazard analysis and monitoring of Critical Control Points.
- In a number of establishments, certain operational/structural hygiene deficiencies were observed on the day of the audit.
- In several cases, deficiencies highlighted by the FSAI audit team had been identified during previous EHO inspections. However, their corrective action was still in progress/outstanding at the time of the FSAI audit.

The audit team was satisfied that in general, official control inspections were identifying non-compliances in food business operator Category 2 classified establishments and were being followed up in accordance with Environmental Health Service protocols and *Guidance Note No. 1*, subject to a number of exceptions identified by the FSAI audit team (see section 4.8).

## **6. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION**

Audit findings requiring corrective action are listed in the corrective action plan. The FSAI recommends that the findings and observations from this audit report should also be addressed in all other PEHO areas, where relevant.

## **7. CONCLUSIONS**

The audit team confirmed that the structure and organisation of Environmental Health Service services and activities were in accordance with the description provided in the *Multi-annual National Control Plan 2012-2016*.

The Environmental Health Service operates as a national service in the HSE which includes regional and local structures to deliver its legal and contractual requirements. At the time of the audit, a system of redistribution of staff between PEHO offices and or Environmental Health Service regions to address *Guidance Note No. 1* requirements was not evident.

At the time of the audit, significant disparities were observed when comparing the number of staff available to complete inspections targets to be achieved, within each of four PEHO offices audited.

As a result of staff resources not being distributed equitably, which directly impacts on performance delivery at local level, a number of PEHO offices fell short of meeting the expected minimum inspection frequency targets to be delivered in accordance with FSAI *Guidance Note No. 1* requirements. On a number of occasions, intervention from the Regional Chief Environmental Health Officer was observed in order to reprioritise and reallocate resources within the PEHO offices.

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Staff reductions and restrictions on filling posts at all levels within the HSE Environmental Health Service (without the possibility of filling posts) posed significant challenges for the organisation in fulfilling all its legal and contractual obligations

Inspection frequency targets were in general, being met for Category 1 and 2 establishments. The target frequencies were however, not achieved in all Category 3, 4 and 5 establishments, which was not in accordance with the planned arrangements to be delivered as part of the FSAI Service Contract, FSAI *Guidance Note No. 1* requirements and the *Environmental Health Business Plan 2012*.

The audit team confirmed that in each of the four PEHO offices, official control sampling activities were being performed in accordance with the risk-based sampling plans for 2012.

Monitoring of official control targets to be met was being carried out at local level within each of the four PEHO offices visited, principally via the compilation of quarterly returns for the Environmental Health Service National Office.

A national review of effectiveness, although planned, had not taken place at the time of the FSAI audit. At local level, evidence reviews process were provided in three of the four PEHO offices visited. However, in one PEHO office, this was not demonstrated and was not considered effective. Consequently, a standardised approach for conducting reviews within the Environmental Health Service offices nationally could not be considered to be fully in place at the time of the FSAI audit.

To illustrate the Environmental Health Service planning and prioritisation process, the *Environment Health Business Plan 2012* was provided to the audit team which outlined the minimum obligations to be met by the Environmental Health Service annually

Consequently, the FSAI audit team's view was that certain minimum statutory obligations to be met by the Environmental Health Service annually (as stated in the *Environmental Health Business Plan 2012*), including targets for the FSAI service contract delivery, were also not being fully achieved in accordance with requirements.

Within the Environmental Health Service, a system of internal audits was not in place at the time of the FSAI audit, which was identified by the FSAI audit team as a weakness in the HSE system of official controls and does not comply with either the requirements of Regulation (EC) No 882/2004 or the FSAI Service Contract.

In general, detailed food safety management systems had been put in place by the food business operators at each of the establishments audited, in order to comply with the requirements of Article 5 of Regulation (EC) No 852/2004 and were being implemented and maintained in accordance with requirements subject to a number of deficiencies and weaknesses identified on the day of the audit. The audit team was satisfied that in general, non-compliances were being identified during the course of inspections and were being followed up in the PEHO offices visited, subject to a number of exceptions identified.

Individual reports of preliminary audit findings for each PEHO office audited were issued following the FSAI audit, which also detailed the corrective actions to be addressed by the Environmental Health Service and have also been summarised again in this report. Any additional findings identified by the FSAI in this report have also been raised with Environmental Health Service management already as part of the delivery of the Service Contract requirements. Consequently, proposed corrective actions and follow-up should reflect their current disposition and status.





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