

AUDIT  
REPORT

Audit of official controls in food business operations catering for high-risk population groups supervised by environmental health officers in the Health Service Executive

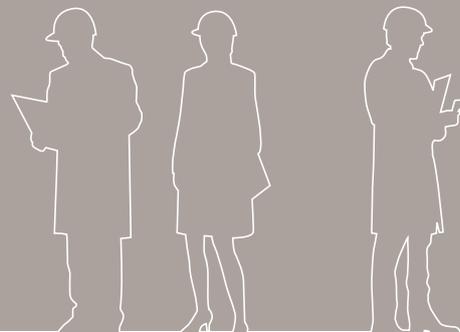
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## 1. GLOSSARY

EHO	Environmental Health Officer
EHS	Environmental Health Service
FSAI	Food Safety Authority of Ireland
GN 1 Rev 2	FSAI Guidance Note No. 1: Guidance for the Health Service Executive on the Inspection of Food Businesses (Revision 2)
HACCP	Hazard Analysis Critical Control Point
HSE	Health Service Executive
MANCP	Multi Annual National Control Plan
PEHO	Principal Environmental Health Officer
SEHO	Senior Environmental Health Officer
WTE	Whole Time Equivalent

## **2. EXECUTIVE SUMMARY**

The Food Safety Authority of Ireland (FSAI) has completed an audit of the food safety controls performed by the environmental health service (EHS) of the Health Service Executive (HSE) in hospitals and crèches<sup>1</sup>. The audit was undertaken as part of the planned programme of audits, carried out by the FSAI in 2012 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 project included an audit in four EHS areas - one in each of the four environmental health regions. The first part of the audit involved an audit of paperwork associated with official controls, including the establishment's files and inspection reports. The second part involved audits of two food business operations (one crèche producing meals onsite and one hospital) in each area.

The audit results were largely positive and the controls in place were generally effective.

Official controls are carried out on a risk basis and at regular intervals in hospitals in the four areas audited. Environmental health officers (EHOs) carry out detailed inspections of the hospitals and the HACCP systems in place.

Official controls are carried out on a risk basis and at regular intervals in crèches in three of the four areas audited. However, in one area audited, a serious breakdown in official food controls for crèches was identified. The scope and frequency of the official controls carried out were not in line with the agreed procedures and did not cover important aspects of food legislation, including inspecting the food business operator's procedures based on HACCP principles and traceability. Eleven crèches notified to that area had never been inspected for food safety controls. The audit team requested corrective actions to be put in place and immediate action was taken by the EHS.

The general hygiene requirements relating to the design, structure, equipment etc. were mostly met in the four crèches audited and checklists for temperature monitoring and cleaning were in place and verified by the EHOs during inspections. Nevertheless, it is a legal requirement for all food businesses to have food safety procedures based on HACCP, in place. HACCP flexibility, which is allowed for in food legislation, is being applied in crèches. However, in three of the four crèches audited, this flexibility was not in accordance with FSAI guidance and was not in compliance with legal requirements<sup>2</sup>. Documented food safety procedures based on HACCP were not in place in three of the four crèches audited and the official controls did not adequately address this. At the time of the audit, the crèches could not adequately demonstrate that the appropriate corrective action would be taken in the event of a food safety non-compliance, e.g. in two of the crèches visited, the temperature readings on the fridge/freezer were outside the expected range and no corrective action was being taken by the food business operator (the fridge was reading between 8-10°C and the freezer was reading -10°C).

In three of the four areas audited, arrangements are in place to inspect higher risk food businesses when EHOs are on extended sick leave or maternity leave. However, in one area, higher risk businesses were only subject to reactive controls and were not scheduled for inspection at the time of the audit. In addition, lower risk food businesses are required to be scheduled for inspection on a less frequent basis but in two of the areas audited, they are not scheduled or inspected as required by documented procedures.

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<sup>1</sup> Only crèches producing meals onsite were included in the scope of the audit.

<sup>2</sup> The audit identified different understandings around the implementation and interpretation of flexibility of GN11 between the FSAI and the HSE.

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Establishments are subject to inspection by the EHS whether they are registered or not. The percentage of establishments registered by the HSE was significantly lower in the area audited in the South region. The procedures in place for following up with food businesses to notify the HSE with a view to registration were not achieving the desired outcome.

Official control regulations require food inspectors to be kept up-to-date and receive regular training. Training for EHOs in local areas is dependent on a national training plan which was developed in 2012 but had yet to be implemented at the time of the audit. Staff interviewed during the audit were knowledgeable of the requirements of the food legislation and also with GN 1 (Rev 2) and EHS protocols.

European Regulations require official control agencies such as the HSE, to carry out internal audits or arrange to have external audits carried out but at the time of the audit, this was not in place. The EHS has committed to developing a system of internal audits in 2013 in line with Article 4(6) of Regulation (EC) No 882/2004 and with the FSAI service contract.

This report makes a number of findings requiring corrective action which, if implemented nationally, will enhance inspections in food businesses.

### 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 HSE in hospital and crèches. 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 assess the delivery and effectiveness of official controls carried out by the EHS in certain businesses catering for high risk consumer groups. The audit focused on how official controls are scheduled, carried out and followed up in the selected establishments.

#### 3.2 Audit Scope

FSAI audits of official controls involve verifying compliance by official agencies with relevant legislation and adherence to the FSAI service contract requirements, as well as relevant documented procedures and the Multi Annual National Control Plan (MANCP). The scope of the audit was the implementation of official controls by the EHS in selected establishments catering for vulnerable groups such as patients in hospitals or children in crèches. The audit focused on how inspections are scheduled, carried out and followed up in selected establishments against the specific requirements of Regulation (EC) No 882/2004. The scope of the audit excluded non-food preparation areas in both the hospitals and crèches. This project involved an audit in four local areas one in each of the four EHS regions: West, South, Dublin North East and Dublin Mid-Leinster<sup>3</sup>. For the purpose of this report, the region and not the local area is referenced.

#### 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 FSAI & the HSE
- Multi Annual National Control Plan for Ireland, 2007-2011
- Health Service Executive Business/Service Plans and data supplied to the FSAI
- EHS National Protocols
- FSAI Guidance Notes

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<sup>3</sup> Each EHS region is made up of 7-9 local health offices.

### **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 (including Article 6.1 of Commission Decision 2006/677/EC) and the FSAI Act.

A pre-audit questionnaire was forwarded to the four areas audited. The purpose of the pre-audit questionnaire was to collate and confirm information regarding official controls and food establishments within each of the areas to be audited.

An evaluation plan was then developed, which provided a detailed overview of the audit including audit scope, objectives, criteria and team. The evaluation plan also included a proposed itinerary for onsite activity. The onsite activity took place in June and July, 2012.

The first part of each of the four audits took place in the principal environmental health officer's (PEHO's) office and involved a review of the information provided as part of the pre-audit questionnaire, as well as an audit of paperwork associated with official controls. The evidence examined as part of the desktop audit included:

- Inspection reports for official control inspections
- Communications, reports and letters to food business operators
- Records of supervisory activities and training carried out by the PEHO and the senior environmental health officer (SEHO)

The second part involved audits of two food business operations (one crèche producing meals onsite and one hospital) in each region. This onsite component verified the delivery and effectiveness of official control activities being carried out as well as an audit of the establishments to determine compliance with food legislation at the time of the visit.

A closing meeting was held at the end of the audit in each area, the purpose of which was 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 in the establishments audited were issued to the EHS regions after the audit for follow-up with the food business operator.

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

### **4.1 Organisation and Structure of Official Controls**

#### **Legal requirements**

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

#### **Findings**

The EHS provides a range of food safety/food control services in accordance with the service contract between the FSAI and the HSE. These services include inspection of food businesses and food sampling to ensure compliance with food legislation, the management of food incidents and a range of compliance building/education measures. The EHS is divided into four geographical regions: Dublin North East, South, West and Dublin Mid Leinster. In each EHS region there are between seven and nine local areas for food control activities, 33 nationally. The EHS operates locally under the supervision of a PEHO. The PEHO organises the supervision of

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food establishments in their functional area. EHOs in three of the four local areas audited are allocated responsibility for the supervision of hospitals in their district. In the area audited in the West region, a senior environmental health officer (SEHO) supervises the hospital. In the area audited in the Dublin North East region, one SEHO was responsible for food control and the Childcare (Pre-School Services) (No.2) Regulations, 2006, in the early year's services. In the areas audited in the South and the West regions, EHOs supervise early year's services in their district. In the area in the Dublin Mid Leinster region, two EHOs spend 50% of their time inspecting early year's services (inspections involve checking compliance with the Childcare (Pre-School Services) (No.2) Regulations, 2006 and food legislation). Table 1 outlines the total number of establishments in the areas audited and the whole time equivalent (WTE) for food control in each of the areas. The number of establishments per WTE in each region is between 160 to 193 establishments.

**Table 1: Overview of Establishment Numbers and WTE in PEHO offices audited**

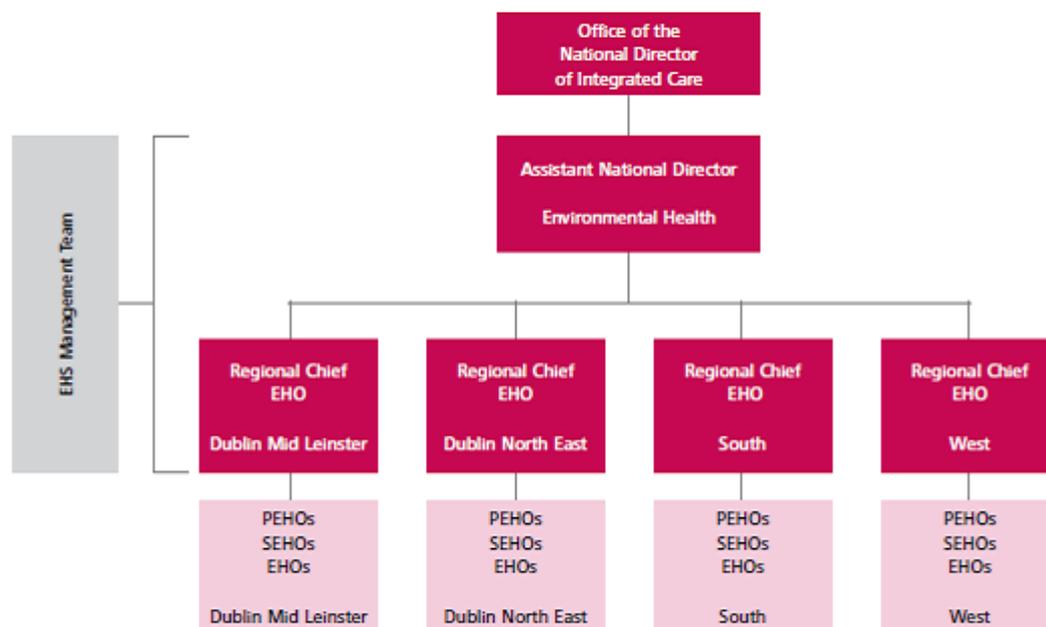
	North East	South	West	Mid Leinster
No of establishments	1,409	2,155	1,693	1,450
Staff resources – WTE EHOs in food control	7.5	13.5	8.75	8.7
Food establishments per WTE EHO	188	160	193	167
	North East	South	West	Mid Leinster
No of crèches	44	15	26	44
No of hospitals	1	2	1	2
Percentage of food establishments registered	80	61	82	89

## 4.2 Coordination and Planning of Official Controls

### Legal requirements

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities. Article 4(5) of the Regulation requires that, when within a competent authority, more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Figure 1: Organisational Structure of the Environmental Health Service



## Findings

Coordination with other competent authorities and between PEHO regions is organised nationally and regionally by the EHS national management team consisting of four Regional Chief EHO and an Assistant National Director for Environmental Health. Coordination between EHOs at local level within a PEHO office is organised by the PEHO. Regular staff meetings of the EHS team take place in each PEHO office. Close liaison between the PEHO and the SEHOs was evident and in each office, the SEHOs meet with the EHOs regularly to review files and assess inspection targets. Due to limited resources the EHS in at least two areas is not scheduling and or inspecting lower risk food businesses: Category 4 and Category 5 establishments as required by GN 1 Rev 2. Different arrangements exist in local areas when EHOs are on extended sick leave or maternity leave. In 3 of the 4 areas audited, higher risk food businesses such as Category 1, 2 and 3 establishments are reallocated to EHOs. In the area audited in the Dublin North East region, at the time of the audit, only reactive work, e.g. to follow up complaints, food incident etc, was carried out when an EHO was on leave.

In the area audited in the Dublin North East region, coordination and planning of the inspections in food businesses excluding early year's services was organised to meet the requirements of GN 1 Rev 2. Staff meetings are held four times annually to review inspection targets and outcomes and a monthly review of data is carried out by the PEHO and the SEHO. Joint inspections take place in problematic food businesses and for night inspections. At the time of the audit, the planning and inspection of early year's services was managed separately to food control and not in line with the requirements of GN1 Rev 2<sup>4</sup>.

In the area in the South region, each EHO's files are reviewed annually or at least once every two years by the PEHO to assess the efficacy and consistency of official controls. The results of the review are relayed at staff meetings. All night inspections are paired and management reviews the pairings every six months to allow different EHOs to work together. EHOs may be requested to inspect food business operators outside their district if inspection targets for those businesses are not met in another district.

<sup>4</sup> Following the audit, the EHS advised that the scheduling planning and frequency of inspection of crèches will be based on GN1 Rev 2 with immediate effect.

In the area audited in the West region, one SEHO has been allocated lead responsibility for food controls and in addition, each SEHO has a team of two/three EHOs which is reviewed annually with a view to changing teams. The SEHO responsible for the IT system carries out a biannual file overview to assess the frequency and outcome of official controls, the results of which are relayed at staff meetings. EHOs may be requested to inspect food business operators outside their district if inspection targets for those businesses are not met in another district. Paired inspections take place for Planned Inspections<sup>5</sup>. Peer reviews of files reviewing risk profiling, inspection records and inspection outcomes take place to assist with consistency and training.

In the area audited in the Dublin Mid-Leinster region, at the end of the third quarter, the SEHOs and the PEHO carry out a full review of targets to ensure Category 1, 2 and 3 food businesses are inspected as required. Food businesses are redistributed amongst EHOs if businesses open/close or as inspection needs require. Each EHO has a monthly inspection plan, and for additional inspections, e.g. where an EHO is on maternity leave, these are agreed between the EHO/SEHO. Monthly, quarterly and end of year file reviews take place between the SEHO and the EHO. The SEHO responsible for the computer system reports a biannual file review for each EHO to assess the frequency and outcome of official controls. EHOs may be requested to inspect food business operators outside their region if inspection targets for those businesses are not met in another region.

### **4.3 Registration of Food Businesses**

#### **Legal requirements**

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business establishments for reviewing compliance with conditions of approval and for the withdrawal of approvals. Article 6 (2) of Regulation (EC) No 852/2004 requires every food business operator to notify the appropriate competent authority with a view to the registration of each establishment.

#### **Findings**

Food businesses are subject to inspection by the EHS whether they are registered or not. The majority of food businesses are registered with the HSE. In the area audited in the South region, the EHS had communicated to food business operators their legal obligation to notify to register with them. However, up to 40% of food businesses were not registered. The procedures in place for following up with food businesses to notify the HSE with a view to registration were not achieving the desired outcome.

All hospitals and crèches reviewed in the areas audited were registered by the HSE.

### **4.4 Prioritisation of Official Controls and Risk Categorisation**

#### **Legal requirements**

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so, account must be taken of identified risks that may influence food safety, past records of food business operator compliance, the reliability of own checks and any additional information on non compliance. Controls shall, in general, be carried out without prior warning.

#### **Findings**

GN 1 Rev 2 sets down the process for risk categorisation of food businesses to determine the frequency of planned inspections. The guidance document also determines the way the EHO shall carry out the inspection and determine the action in the case of non-compliance. In addition, it sets down the criteria for prioritising inspections. The document aims to facilitate a consistent approach within the EHS in prioritising and conducting inspections of food businesses aimed at verifying and/or securing compliance by food business operators with relevant food legislation.

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<sup>5</sup> Planned Inspections are defined in GN1 Rev 2 as having regard to each of the four elements of the food safety management system and relevant food law (other than general hygiene) applicable to a food business.

Implementation of GN 1 Rev 2 commenced during 2011 and in some areas, at the beginning of 2012. A priority action list<sup>6</sup> is in place in all of the areas audited. All hospitals and crèches are risk profiled. In all areas, hospital inspections were carried out as per GN 1 Rev 2. In three of the areas audited, the crèche inspections were carried out based on risk and at regular intervals and all crèche files reviewed have been inspected in 2011 or 2012.

In the area audited in the Dublin North East region, the frequency of inspection for crèches is on a rolling timeframe and is not risk-based. Reactive inspections do however, take place as a result of a complaint or a food related incident. Eleven crèches notified to the HSE in the North East between September 2010 and April 2012 had never been inspected. One crèche had not been inspected since 2007, two crèches had not been inspected since 2008 and a further four crèches had not been inspected since 2009<sup>7</sup>.

## **4.5 Documented Procedures**

### **Legal Requirements**

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.

### **Findings**

In December 2011, the EHS management team launched a system of national protocols. The objective of the protocols is to harmonise work practices across all PEHO areas. Implementation of the protocols was requested by EHS management to be completed by March 2012. The EHS is currently developing a national EHS IT system which is expected to be rolled out to all regions during 2013. In the interim, EHS IT systems locally have been modified to allow GN 1 Rev 2 to be implemented, with certain limitations in some areas. In the area in the West region, the IT system has been adapted to implement GN 1 Rev 2, its related forms/records and allowing any non-compliance identified to be classified. In the area in the South, the local inspection checklist is being used until the national IT system is in place. Non-compliances are classified manually using a non-compliance record. In the areas audited in the Dublin North East and the Dublin Mid-Leinster regions at the time of the audit, non-compliances were not classified in accordance with the guidance.

Overall, GN 1 Rev 2 was being implemented and inspection outcomes were applied for hospital and crèche inspections. However, elements of the national business protocol are not being implemented in some areas until the national IT system is in place.

GN 1 Rev 2 was not used for crèche inspections in the Dublin North East area audited. A standardised inspection tool, developed nationally under the Childcare (Pre-School Services) (No.2) Regulations, 2006, and a locally developed checklist are used. The scope of the official controls being carried out were not in line with the agreed GN 1 Rev 2 and do not cover aspects of Regulation (EC) No 852/2004, including inspecting the food business operator's procedures based on HACCP principles and traceability. When an inspection in a crèche is carried out a letter is issued by the EHS identifying the non-compliances found. Follow-up action to close out the non-compliances is taken at the next inspection. From a review of the files it was seen that follow-up was very often three years later. However, if the non-compliances found posed a risk to public health, a follow-up visit was scheduled sooner<sup>8</sup>.

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<sup>6</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.

<sup>7</sup> The HSE advised the FSAI immediately after the audit that corrective action had commenced on inspections and files in crèches as an urgent priority.

<sup>8</sup> After the audit, the HSE advised that official food control in crèches in the area will, with immediate effect, be carried out using GN1 Rev 2, Business Protocol 3 and will include all requirements of Regulation 852/2004.

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

### Legal Requirements

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 cases 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.

### Findings

Copies of inspection reports were available for all establishments audited. The essential official control information is recorded in the local EHS 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 Dublin North East, West and the South regions, the food business operators receive a report after all inspections in both hospitals and crèches. In the area in the Dublin Mid-Leinster region, inspection reports are issued when non-compliances are identified as per EHS business protocol 3 'Inspection of a Food Business'.

The detail of the information in the reports to food business operators varies from purely outlining non-compliances to providing a detailed and informative report of the inspection. In some cases, the legislative breach was indicated for each non-compliance and in other reports, the title of the legislation breached was at the top of the letter only. In each of the four areas audited, timeframes for non-compliances to be remedied were included on hospital reports. However, this was not generally recorded on crèche reports. Different systems were in place in the four areas audited to record the close out of non-compliances at the next inspection. On the new Food Business Inspection record, part of protocol 3 'Inspection of a Food Business', the sentence "*Any infringements highlighted on previous visit must be reviewed*" is included. However, it was not always transparent how this is done as it was not always recorded. In the area audited in the North East region, a note was made on the previous inspection letter or the food business operator corrective action report which highlights that the EHO followed up and closed out non-compliances at the next inspection for both crèches and hospitals. In the hospital report in the area audited in the West region, a note was made on the letter that previous non-compliances had been examined.

## 4.7 Staff Performing Official Controls

### Legal Requirements

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authorities 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.

### **Findings**

Historically, the EHS arranged training locally and between a number of PEHO areas. In each of the areas audited, a training record is kept on file for each EHO. Training (cascade training) is carried out informally in regions by SEHOs or EHOs that are on national working groups. A training database is in place in the area in the North East region.

Training in local areas is now dependent on a national training plan which was developed in 2012 but had yet to be implemented at the time of the audit. Staff interviewed during the audit were knowledgeable of the requirements of the national and EU legislation requirements and also with GN1 Rev 2 and EHS protocols. However, sufficient formal training was not in place at the time of the audit to ensure staff are kept up-to-date in their area of competence.

A training needs assessment has been completed for EHS staff in 2009 and 2011 and this has been returned for inclusion in the national training plan 2012-2013.

## **4.8 Verification and review of official controls and procedures**

### **Legal Requirements**

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. These must be subject to independent scrutiny and carried out in a transparent manner. Article 8(3) states that the competent authorities must 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.

### **Findings**

Verification and review of official controls is organised locally by the PEHO and/or SEHOs and was generally effective. Different arrangements were in place in the areas audited including:

- File reviews, which are conducted periodically by PEHOs or SEHOs to ensure: the consistency and quality of inspections, inspection targets are being met and inspections are carried out, reported on and in line with legislative requirements
- Regular staff meetings and management meetings held to discuss enforcement issues and inspection activities
- Data reviews of inspection activities carried out are summarised periodically
- EHOs provide monthly returns to present an overview of inspections carried out
- In some areas, the SEHOs carry out onsite visits with EHOs on a regular basis and in other areas, a SEHO accompanies an EHO in the event of a serious problem in a food establishment
- Joint inspections in higher risk establishments for planned inspections and in some management review the teams every six months to allow different EHOs to work together.
- In one area, as part of staff training and to facilitate consistency, peer review of files takes place (see Section 4.2 Findings).

Internal audits were not in place but the HSE EHS has committed to developing a system of internal audits in 2013 in line with Art. 4(6) of Regulation (EC) No 882/2004 and the FSAI service contract. The only audits of the HSE being carried out under Article 4(6) were those performed by the FSAI as external audits of the HSE. FSAI audits do not substitute for the competent authority's responsibility to implement the requirements of Art. 4(6). The statutory basis for FSAI audits is contained in Section 48(9) of the FSAI Act). The area audited in the West region is developing a compliance building auditing process along with the introduction of the EHS protocols. The purpose of this process will be to facilitate the consistent implementation of EHS protocols in the area.

## **5. OFFICIAL CONTROLS PERFORMED IN FOOD ESTABLISHMENTS**

### **5.1 Crèches**

#### **5.1.1 Crèche - General and specific hygiene requirements**

##### **Legal requirements**

Article 4(2) of Regulation (EC) No 852/2004 establishes that the food business operator carrying out any stage of production, processing and distribution of food after the stage of primary production/associated operations shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, siting and size of food premises.

##### **Findings**

The general hygiene requirements relating to the design/layout, structure, equipment and facilities were generally met in the four establishments audited or deficiencies had been identified as requiring improvement/correction by the competent authority before this audit. In all of the establishments audited, checklists for temperature monitoring and cleaning and disinfection were in place and verified during official control inspections by the competent authority. EHOs in all regions checked staff training as part of their official controls and this was recorded in their notes. There were no systems or procedures in place in the four crèches relating to fitness to work after illness. Official controls did not identify this as a shortcoming in any of the establishments audited.

#### **5.1.2 Crèche - Procedures based on HACCP principles**

##### **Legal requirements**

On the basis of Article 5 of Regulation (EC) No 852/2004, the food business operator shall 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.

##### **Findings**

Documented procedures based on HACCP were in place in one of the four crèches audited. In the other crèches audited, checklists, but not procedures, were in place for temperature monitoring, and cleaning/disinfection. The checklists were verified during official controls by the competent authority with improvements being requested in all cases. At the time of the audit, the food business operators in crèches could not adequately demonstrate that appropriate action would be taken if a critical limit went out of control. HACCP flexibility, which is allowed for in food legislation, is being applied in crèches. However, in three of the four crèches audited, this flexibility was not in accordance with Guidance Note 11: Assessment of HACCP Compliance and not in compliance with legal requirements. In three of the four crèches audited, the food business operator's controls required strengthening. In two of the crèches visited, the temperature readings on the fridge/freezer were outside the expected range and no corrective action was being taken by the food business operator (the fridge was reading between 8-10°C and the freezer was reading -10°C). Shortcomings in relation to the food business operator controls which had previously been identified during official control inspections around thawing, hot holding, training and calibration, were also identified in crèches during the audit.

### **5.1.3 Crèche - Traceability**

#### **Legal requirements**

According to Article 18 of Regulation (EC) No 178/2002, the traceability of food and food producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The food business operator shall have in place systems and procedures to identify from whom they have been supplied.

Schedule 2 of European Communities (General Food Law) Regulations, 2007 (S.I. No. 747 of 2007 as amended) requires the food business operator shall, as a minimum, maintain records of the following:

- (a) In relation to food supplied to the food business operator -
  - (i) Name of supplier
  - (ii) Address of supplier
  - (iii) Nature of products supplied, and
  - (iv) Date of transaction/delivery

#### **Findings**

The traceability in place in the crèches audited varied and the type of information requested by the competent authority to ensure traceability also varied. In three of the crèches audited, some form of traceability was in place and official control reports in two of these establishments had requested further information to be maintained. In the crèche in the Dublin North East region, there were no records of food deliveries in place, although the official control report had requested a supplier list be maintained.

## **5.2 Hospitals**

### **5.2.1 Hospitals - General and specific hygiene requirements**

#### **Legal requirements**

Article 4(2) of Regulation (EC) No 852/2004 establishes that the food business operator carrying out any stage of production, processing and distribution of food after the stage of primary production/associated operations, shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, siting and size of food premises.

#### **Findings**

The general hygiene requirements relating to the design/layout structure, equipment and facilities were generally met in the four hospitals audited or any non-compliances noted by the audit team were previously identified by the competent authority in official control reports. A system of continuous improvement or review was in place in each of the hospital's own food safety management systems. There were procedures in place in the four hospitals relating to fitness to work, cleaning and disinfection, food hygiene training and pest control. There were extensive procedures in place in all of the hospitals audited to ensure the cold chain is monitored and controlled and hot foods were held at correct temperatures.

In the four hospitals audited, a system of trolleys deliver the food from the main kitchen to satellite kitchens on the wards. Programmes were in place to clean and maintain the trolleys in all of the four hospitals.

### **5.2.2 Hospitals - Procedures based on HACCP principles**

#### **Legal requirements**

On the basis of Article 5 of Regulation (EC) No 853/2004, the food business operator shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

#### **Findings**

HACCP based procedures were in place in all the establishments audited and were found to be meeting the legal requirements. The competent authorities identified the shortcomings of the HACCP systems in place in the hospitals in inspection reports in three of the four hospitals audited.

### **5.2.3 Hospitals - Traceability**

#### **Legal requirements**

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The food business operator shall have in place, systems and procedures to identify from whom they have been supplied (see 5.1.3).

#### **Findings**

Traceability was in place as required by Article 18 of Regulation (EC) No 178/2002 and with a few minor exceptions the systems in place were satisfactory. All areas reviewed the traceability systems in the hospitals audited and this was documented in the official control files.

## **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, where relevant, be addressed in all other PEHO areas.

## **7. CONCLUSIONS**

The HSE has established GN 1 Rev 2, for the organisation of inspections in food establishments. With the exception of one area audited, all of the areas audited were generally applying this guidance to the planning and implementation of inspections. In line with legal requirements, food business operators receive a report following an inspection, at least in the case of non-compliance. Staff are familiar with the legal requirements and there is good cooperation between EHOs within offices to facilitate a consistent approach to official controls. Training in local areas is dependent on a national training plan which was developed in 2012 but had yet to be implemented at the time of the audit. Different arrangements exist in areas to provide cover when EHOs are on extended sick leave or maternity leave: in some areas higher risk establishments such as Category 1, 2 and 3 establishments are reallocated to EHOs but in one area audited only reactive work is carried out. The percentage of establishments registered by the HSE was significantly lower in the area audited in the South region although establishments are subject to inspection by the EHS whether they are registered or not. The system of internal audits had not been implemented at the time of this audit and there were different systems in place locally for the verification of the effectiveness of official controls.

### **Crèches**

In three regions, crèches were supervised generally in line with GN 1 Rev 2. However, in one area, a serious breakdown in official food controls<sup>9</sup> was identified.

HACCP flexibility, which is allowed for in food legislation, is being applied in crèches. However, in three of the four crèches audited, this flexibility was not in accordance with *Guidance Note 11: Assessment of HACCP Compliance* and was not in compliance with legal requirements. Two crèches were not in compliance with the legal requirements for traceability and the official controls had not identified this.

### **Hospitals**

In the four regions audited hospitals were inspected in line with guidance and documented procedures. Detailed inspection reports were issued with timeframes provided for the food business operator to complete corrective action.

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<sup>9</sup> For the Dublin North east office, the HSE advised following the audit that work has commenced on inspections and files reviews as an urgent priority. Supervision of crèches to be carried out in line with GN 1 Rev 2.





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