

AUDIT  
REPORT

Audit of Official Controls  
carried out by the Health  
Service Executive  
(Regulation (EC) No 853/2004)

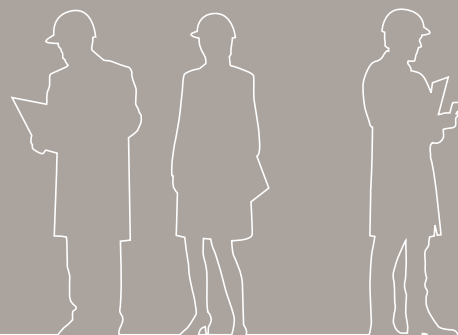
NOVEMBER 2017



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## 1. GLOSSARY

EHO	Environmental Health Officer
FSAI	Food Safety Authority of Ireland
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) is responsible for the enforcement of all food legislation in Ireland, which is carried out through service contracts with official agencies. The Health Service Executive (HSE) is responsible for official controls in approximately 45,500 food businesses in Ireland. As part of its legal mandate, the Food Safety Authority of Ireland is required to verify that the system of official controls is working effectively.

This audit was carried out to assess the effectiveness and appropriateness of official controls conducted by the HSE in establishments which have been approved under Regulation (EC) No 853/2004. At the time of this audit, there were 40 such approved establishments under the supervision of the HSE. The audit focussed on food businesses that had already received approval and included assessment of the official controls being applied in these establishments as well as the process used for approval. Food businesses that had been identified as likely to require approval but had not yet entered the approval process, were excluded from the scope of this audit.

Audits were conducted in four local areas which comprised a review of all files and paperwork associated with official controls relevant to approved establishments, including information in relation to inspections, sampling and other official control records. The audit team visited six approved establishments accompanied by the relevant environmental health officers (EHOs), to assess the implementation of official controls and also to confirm the food business operator's compliance with food law.

A structured approach for the organisation of staff, planning and coordination of official controls was in place within the HSE with regards to approved establishments. The Environmental Health Information System (EHIS) is used to schedule future inspections and also to monitor progress on planned inspections. In each of the local areas audited, there were regular reviews by principal environmental health officers (PEHOs) and senior environmental health officers (SEHOs) of planned inspection frequency as well as reviews of the official controls being carried out in approved establishments. Evidence of decisions and information from national specialist committees being disseminated to local areas to ensure consistent implementation of official controls in approved establishments was seen during the audit.

Records of the approval application, approval recommendation from the PEHO and notification to the FSAI for approval number as well as a copy of the approval certificate, were maintained on the files of the eleven approved establishments for which file review was conducted. No application for approval had been refused and no approvals had been suspended or restricted at the time of the audit. Eleven approvals had been revoked, ten due to the approved establishment ceasing to trade and one due to a change in activities being carried out, which meant that the establishment no longer required approval. Evidence of notification to the FSAI (for the purposes of updating the national list of approved establishments under the supervision of the HSE) was maintained on the files for the approved establishments. However, errors were identified in relation to the information recorded by the FSAI as part of the list of approved establishments published on the FSAI website.

During the on-site verification in the approved establishments, the audit team assessed whether the food business operation was operating in-line with the requirements of the approval granted. Five of the six establishments were operating in line with the requirements of the approval granted. One establishment was not approved for porcine species however, it was processing pork. The approval for this establishment was amended to include porcine species immediately following the on-site work.

It is a requirement of food law that that official controls are carried out regularly, on a risk basis, with appropriate frequency and without prior warning. Each of the eleven approved establishments for which a file review was conducted, had been risk assessed and had a risk category assigned to them as per *Guidance Note No. 1 Guidance for the Health Service Executive on the Inspection of Food Businesses (Revision 2)* (GN1). The inspection target set for approved establishments is two planned inspections per annum. In 2015 and 2016, the percentage of approved establishments on or above the minimum inspection target was 67.5% on a national basis. Each of the 40 approved establishments under the supervision of the HSE had been inspected in 2016. In the four local areas audited, the percentage was 82.5% of approved establishments on or above the minimum inspection target. The EHOs indicated that in some instances, although it was intended to conduct a planned inspection, that this was not always possible due to the size and complexity of the food business, or if the relevant personnel were not present while inspections were being conducted, that access to all records and paperwork was not always possible. This meant that the inspection would not meet all of the criteria of an 853 planned inspection; and so were recorded as an 853 surveillance inspection. In the four local areas that were subject to audit, the two establishments that did not meet the minimum inspection target had been subject to planned surveillance inspections, in addition to one 853 planned inspection.

In three of the four local areas audited, official control inspections of approved establishments were carried out without prior warning (with the exception of advisory visits, or inspections where specific persons or information are required to be present). In the other local area, in line with the more formal audit approach adopted in relation to this approved establishment, official controls were notified to the food business operator in some cases. In 2015 and 2016, one inspection, from a total of five, was carried out without prior warning. The EHOs indicated that this was necessary to allow for assessment of paperwork prior to inspection, and also to ensure that relevant food business operator personnel were available. The audit team considered this to be a reasonable approach to conducting official controls in this establishment, due to the size and complexity of the operation. However, consideration should be given to the inclusion of aspects of official controls conducted without prior warning.

The review of the approved establishment files in each of the local areas confirmed that when non-compliances with food law are identified during official control inspections, the food business operator is notified and follow-up action is taken by the Environmental Health Service, as appropriate. During the on-site verification in the approved establishments, the audit team assessed whether the approved establishment was operating at a standard required of an approved establishment. The audit team determined that all of the approved establishments in which on-site verification was conducted, were operating to a standard required of an approved establishment, though shortcomings requiring corrective action were identified in five of the six establishments.

Overall, the audit concluded that the official controls carried out by the Environmental Health Service in approved establishments are structured and well-organised. Non-compliances identified during official control inspections were promptly communicated to the food business operator and were effectively followed up on subsequent inspections.

## 3. INTRODUCTION

### 3.1. Audit Objective

The FSAI is responsible for enforcement of 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 is one of the agencies that has entered into a service contract with the FSAI and is responsible for enforcement of food legislation in approximately 45,500 food businesses in Ireland. It is a requirement of food legislation and the service contract that the HSE ensures that official controls are carried out regularly, on a risk basis and at an 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 systems of official controls put in place by the official agencies are working effectively. This audit was carried out to assess the effectiveness and appropriateness of official controls conducted by the HSE in approved establishments.

Food businesses that handle and/or process foods of animal origin may also require approval from the competent authority. Examples of food businesses that are under the supervision of the HSE and require approval, include meat processors and meat product manufacturers. At the time of this audit, there were 40 such approved establishments under the supervision of the HSE. This audit focussed on food businesses that had already received approval and included assessment of the official controls being applied in these establishments as well as the process used for approval. Food businesses that had been identified as likely to require approval, but had not yet entered the approval process, were excluded from the scope of this audit.

On-site verification of compliance with food law in six approved establishments was assessed as part of this audit.

This report describes the audit's objective, scope, methodology and findings. The audit was carried out in each of the four operational regions of the HSE's Environmental Health Service.

### 3.2. Audit Scope

The audit covered the organisation, planning, coordination, implementation and review of official controls at national level, as they applied to approved establishments; in order to confirm compliance with the requirements of Regulation (EC) No 882/2004, the service contract between the FSAI and the HSE, the national control plan for Ireland 2012-2016 and the HSE's own documented procedures. The audit comprised audits at central level, four local areas and in six approved establishments.

### 3.3. Audit Criteria and Reference Documents

- [Food Safety Authority of Ireland Act, 1998](#) (S.I. No. 29 of 1998), as amended.
- [Service Contract between the FSAI and the HSE](#)
- [National Control Plan for Ireland 2012-2016 \(MANCP\)](#)
- [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 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 852/2004](#) on the hygiene of foodstuffs, as amended
- [Regulation \(EC\) No 853/2004](#) laying down specific hygiene rules for food of animal origin, as amended
- [Regulation \(EC\) No 854/2004](#) laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, as amended
- [Regulation \(EC\) No 2073/2005](#) on microbiological criteria for foodstuffs, as amended
- [S.I. No. 432 of 2009: European Communities \(Food and Feed Hygiene\) Regulations, 2009](#)
- [Regulation \(EU\) No 1169/2011](#) on the provision of food information to consumers.
- HSE Environmental Health Service Business Plans and data supplied to the FSAI
- HSE Environmental Health Service Documented Procedures
- Guidance Notes/Codes of Practice
- Other relevant other relevant legislation detailed in the FSAI Service Contract with the HSE

### 3.4. Audit Methodology

This audit of official controls was undertaken using the audit procedures documented in the FSAI's Quality Management System. These procedures implement the FSAI's audit obligations, defined in Schedule 5 of the service contract between the FSAI and the HSE, and in accordance with the requirements of Regulation (EC) No 882/2004, Commission Decision 2006/677/EC, and Section 48(9) of the Food Safety Authority of Ireland Act, 1998, as amended.

Before the audit, the HSE completed a pre-audit questionnaire in respect of information regarding the approved establishments under its supervision. An evaluation plan describing the audit process and approach including the scope, objectives, criteria and the audit team, was sent to the HSE. The audit commenced with an opening meeting and audit with the HSE at central level. The audit team assessed, on a national level, how the Environmental Health Service delivers its obligations under the service contract, implements Regulation (EC) No 882/2004 and adheres to documented procedures with regards to the supervision of approved establishments.

Audits were then conducted in four local areas which comprised a review of all files and paperwork associated with official controls relevant to approved establishments; including information in relation to inspections and sampling and other official control records. The audit team then visited approved establishments in each local area, accompanied by the relevant EHOs, to assess the implementation of official controls and also to confirm the food business operator's compliance with food law. The audit findings relevant to each approved establishment were communicated to the food business operator and the Environmental Health Service.

A final closing meeting was held at central level where the findings of the audit were discussed.



## 4. AUDIT FINDINGS

### 4.1. Official Controls Performed in Accordance with Regulation (EC) No 882/2004

#### 4.1.1. Organisation and Structure of Official Controls

**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 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. It is managed nationally by an Assistant National Director, regionally by four regional chief environmental health officers (RCEHOs) and locally by PEHOs. Targets for conducting official controls in HSE supervised establishments (including approved establishments) are set as part of the business planning process and are outlined in the Environmental Health Service Annual Business Plan. Official controls for approved establishments are generally conducted in line with GN 1<sup>1</sup>. Depending on the nature and complexity of the approved establishment and the associated activities being carried out, adjustment to the manner in which official controls are conducted may be made by the PEHO.

There were 40 approved establishments under the supervision of the Environmental Health Services at the time of this audit. A structured approach for the organisation of staff for the performance of official controls was in place within the Environmental Health Services with regards to carrying out official controls in approved establishments. EHOs carrying out official controls in approved establishments were authorised as required and warrants were verified.

#### 4.1.2. Coordination and Planning

**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.**

#### Findings

Official controls implemented by the Environmental Health Service are conducted on a risk basis and inspections are scheduled in line with the requirements of GN 1 through the EHIS.

Evidence of communications between national level, local areas and then onwards to EHOs were seen in the four local areas regarding official controls being implemented in approved establishments. Minutes and agendas of

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<sup>1</sup> [FSAI HSE Guidance for the Health Service Executive on the Inspection of Food Businesses ~ Revision 2](#)

staff meetings and attendance at training where topics relevant to the supervision of approved establishments were discussed were provided in each of the four local areas. Specialist committees are in place to coordinate queries on a national level, which can be raised from any of the local areas but which may have relevance to the implementation of official controls in approved establishments in other local areas. Decisions and information from these specialist committees is disseminated on a national basis to ensure consistent implementation of official controls in approved establishments.

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls in the approved establishments. The EHIS is used to schedule future inspections and also to monitor progress on planned inspections. In each of the local areas audited, there were regular reviews on the EHIS with a view to identifying establishments which have fallen behind the assigned inspection frequency. Reviews of the official controls being carried out in approved establishments were also carried out by PEHOs and SEHOs on a regular basis.

#### **4.1.3. Registration and Approval**

**Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments. In addition, it requires competent authorities to draw up and keep up-to-date, a list of food business operators which have been registered.**

**Article 3 of Regulation (EC) No 854/2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation 882. In addition, Article 3(3) states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.**

**Under the service contract between the FSAI and the HSE, official controls of food businesses subject to under Regulation (EC) No 853/2004 must be carried out in line with the Authority guidance on approvals under Regulation (EC) No 853/2004 of establishments supervised by HSE consistent with similar/equivalent official controls carried out by other official agencies, as coordinated through the Authority.**

**The service contract requires that the official agency shall grant/withdraw/suspend/amend the approval in accordance with the provisions of food legislation, the Authority's guidance and official agency procedures. The official agency shall notify the Authority without delay of changes to establishment approvals to facilitate publication of an up to date list on the Authority's website.**

#### **Findings**

At the time of this audit, there were 40 approved establishments under the supervision of the HSE. Evidence of the procedures and related records used in the approval of these establishments was assessed in each of the four local areas. Approval numbers had been provided to each of the approved establishments as part of the approval process. The list of approved establishments is maintained as part of the EHIS. However, errors were identified in relation to the information recorded by the FSAI as part of the list of approved establishments published on the FSAI website.

Records of the approval application, approval recommendation from the PEHO and notification to the FSAI for approval number as well as a copy of the approval certificate, were maintained on the files of the eleven approved establishments for which file review was conducted.

No application for approval had been refused and no approvals had been suspended or restricted at the time of the audit. Eleven approvals had been revoked, ten due to the approved establishment ceasing trading and one due to a change in activities being carried out, which meant that the establishment no longer required approval.

Evidence of the revocation of the approvals was provided by the Environmental Health Service.

Four of the eleven approved establishments for which file review was conducted were granted conditional approval prior to receiving their full approval. Seven approvals had been amended to reflect changes in the food business operators' activities, the species being processed and a change to the company name.

Two of the eleven approved establishments had conditions applied to the full approval, one of which was to limit the quantity produced in the food business operation, and the other was to require prior notification to the Environmental Health Service of any significant changes to the nature and extent of the business.

The information relating to approved establishments and the approval of such establishments is maintained in the EHIS and also in hard copy files. Changes to the status of the approval are notified to the RCEHO, the Environmental Health Service national office and the FSAI. Evidence of notification to the FSAI (for the purposes of updating the national list of approved establishments under the supervision of the HSE) was maintained on the files for the approved establishments.

During the on-site verification in the approved establishments, the audit team assessed whether the food business operation was operating in line with the requirements of the approval granted. Five of the six establishments were operating in line with the requirements of the approval granted. One establishment was not approved for porcine species however, it was processing pork. The approval for this establishment was amended to include porcine species immediately following the onsite work.

#### **4.1.4. Prioritisation of Official Controls and Risk Categorisation**

**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 operators, the reliability of own checks and any additional information on non-compliance.**

**Article 3(2) of Regulation (EC) No 882/2004 requires that official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an *ad hoc* basis.**

**The service contract between the FSAI and the HSE requires that approved establishments must be risk categorised to determine the frequency of inspection in accordance with legislative requirements and that the Authority will be consulted in advance of any national planned change to the frequency of inspections in Guidance Note No.1. The service contract also requires that inspections must be carried out in accordance with legislative requirements, the Authority guidance and Official Agency procedures. The inspection process should be carried out in accordance with the Authority's Guidance Note No. 1. The official agency shall keep the approval of establishments under review when carrying out official controls.**

### Findings

File review was conducted by the audit team on eleven approved establishments in the four local areas audited. The review of the files included an examination of the information relating to the risk assessment for the approved establishments. Each of the eleven approved establishments had been risk assessed and had a risk category assigned to them as per GN 1. Six of the eleven establishments (for which file review was carried out) were Category 1, four were Category 2 and one was Category 3. The inspection target set for approved establishments is two planned inspections<sup>2</sup> per annum.

In 2015 and 2016, the percentage of approved establishments on or above the minimum inspection target was 67.5% on a national basis. Each of the 40 approved establishments under the supervision of the HSE had been inspected in 2016. In the four local areas audited, the percentage was 82.5% on or above the minimum inspection target.

The EHOs indicated that in some instances, although it was intended to conduct a planned inspection, that this was not always possible due to the size and complexity of the food business, or if relevant personnel were not present while inspections were being conducted, that access to all records and paperwork was not always possible. This meant that the inspection would not meet all of the criteria of an 853 planned inspection; and so were recorded as an 853 surveillance inspection. In the four local areas that were subject to audit, the two establishments that did not meet the minimum inspection target had been subject to planned surveillance inspections, in addition to one 853 planned inspection.

Each local area has a Priority Action List to ensure that businesses that potentially pose a more immediate risk to public health receive on-going attention. None of the approved establishments in each of the four local areas audited were of a standard to warrant placement on the priority action list, at the time of this audit.

In three of the four local areas audited, official control inspections of approved establishments were carried out without prior warning (with the exception of advisory visits, or inspections where specific persons or information is required to be present). In the other local area, in line with the more formal audit approach adopted in relation to this approved establishment, official controls were notified to the food business operator in some cases. In 2015 and 2016, one inspection (from a total of five) was carried out without prior warning. The EHOs indicated that this was necessary to allow for assessment of paperwork prior to inspection, and also to ensure that relevant food business operator personnel were available. The audit team considered this to be a practical approach to conducting official controls in this establishment, due to the size and complexity of the operation. However, consideration should be given to the inclusion of aspects of official controls conducted without prior warning.

The Regulation 853 visit record sheet includes a prompt for the EHO to review the approval status during official control inspections. The EHOs indicated that the approval status of the establishment is reviewed during official control inspections and evidence of this was maintained on the establishment files. Three of the six approved establishments selected for on-site verification had been the subject of formal reviews of their activities and the suitability of their approval, which had resulted in two approvals being subsequently amended.

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<sup>2</sup> Planned inspections are defined in FSAI HSE Guidance for the Health Service Executive on the Inspection of Food Businesses ~ Revision 2: A Planned Inspection is conducted having regard to each of the aspects in the four elements of the food safety management system (A - D) and relevant food law (other than general food hygiene) applicable to the individual food business (E). Inspection types 2 - 4 may also be considered as a Planned Inspection where they meet the criteria.

#### 4.1.5. 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 and must keep these procedures up-to-date.

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

The Environmental Health Service has documented a suite of national protocols for use by the EHOs in carrying out official controls. The following Environmental Health Service protocols were deemed relevant to this audit:

- Protocol 2 853 Registration and Approval
- Protocol 3 Inspection of a Food Business
- Protocol 4 Food Complaints
- Protocol 5 Food Business Complaints
- Protocol 8 Food Sampling
- Protocol 9 Food Alerts
- Protocol 11 Food Enforcement Procedure

It was confirmed that these protocols were used in carrying out official controls and there was evidence on the approved establishment files of use of these protocols and the related records. The EHOs were very familiar with the additional requirements for an 853 inspection and had covered these (identification mark on packaging, temperatures for minced meat, sourcing from approved suppliers only) during inspections of approved establishments. However, in one of the local areas, it was noted that an incorrect visit record was used to record the inspection on three occasions.

#### 4.1.6. Identification, Follow-up and Close-out of Non-compliances

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies 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 with regard to non-compliance.

Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed.

#### Findings

The review of the approved establishment files in each of the local areas confirmed that when non-compliances with food law are identified during official control inspections the food business operator is notified and follow-up action is taken by the Environmental Health Service, as appropriate. The records relating to subsequent inspections provided evidence that non-compliances are assessed for close-out by the EHOs during the next inspection in each of the four local areas.

In the six approved establishments visited as part of the on-site verification, it was evident that when non-compliances are identified during official control inspections, there is prompt communication of the non-compliances with food law to the food business operators and that corrective actions are monitored closely during subsequent inspections.

Where food businesses are not complying with food law, the Environmental Health Service can take enforcement action, proportionate to risk, to secure compliance with the legal requirements to ensure consumer protection. Enforcement action may include the following: Improvement Notice, Improvement Order, Prohibition Order, Closure Order or Prosecution. At the time of this audit, there had been one enforcement action taken in one of the 40 approved establishments in 2014; no enforcement action had been required in any of the approved establishments in 2015 or 2016.

During the on-site verification in the approved establishments, the audit team assessed whether the approved establishment was operating at a standard required of an approved establishment. The audit team determined that all of the approved establishments in which on-site verification was conducted, were operating a standard required of an approved establishment, though shortcomings requiring corrective action were identified in five of the six establishments.

#### **4.1.7. Reports to Food Business Operators**

**Article 9 of Regulation (EC) No 882/2004 requires that competent authorities 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.**

#### **Findings**

It was noted during the review of the files for the eleven approved establishments, that reports are sent to the food business operator following on-site inspections when non-compliances are identified, as per the national protocol. These reports specified the non-compliances identified and the requirement for corrective action to be carried out by the food business operator.

#### **4.1.8. Verification and Review of Official Controls and Procedures**

**Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.**

**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 the 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.**

## Findings

The Environmental Health Service has developed a position paper regarding the effectiveness of official controls which details the objectives and goals with regards to ensuring that official controls are effective and appropriate. In each of the four local areas audited, systems to verify the effectiveness of official controls carried out in the approved establishments were in place. These included regular file reviews conducted by either the PEHO or SEHO with each of the EHOs. As the number of approved establishments in each of the local areas is small, official controls being carried out in such establishments are kept under review by the PEHO and SEHO. There was also evidence of open communications between the EHOs and the SEHO/PEHO regarding any issues that arise as well as inspection outcomes. Evidence was seen during file review of joint inspections of approved establishments where two officers conducted the official controls.

The Environmental Health Service established an internal audit function in 2015 and conducted one audit in 2016.

### 4.1.9. Staff Performing Official Controls

**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.**

## Findings

Staff in the four local areas were knowledgeable of the requirements of national and EU legislation requirements and also with GN1 and the Environmental Health Service protocols. Training in local offices is facilitated through the national training plan which is developed annually. The EHOs who carry out official controls in the approved establishments have attended training relevant to the activities and official controls being carried out in approved establishments. Evidence of dissemination of information was seen during the audit, following training attended by EHOs at staff meetings. This took the format of presentations and discussions regarding topics of relevance to official controls in approved establishments. Additionally, the local areas also maintained shared drives, whereby information and presentations from training are retained and accessible to all staff.

## 4.2. Food Business Operator Findings

A report was provided to each local area of the findings identified during the on-site verification in each of the approved establishments audited.

### 4.3. Audit Findings ~ Local Area Wicklow

#### Organisation and Structure of Official Controls

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.

Article 4(2) The competent authorities shall ensure: that

- They have, or have access to, an adequate laboratory capacity for testing
- A sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively
- Appropriate and properly maintained equipment and facilities
- Legal powers to carry out official controls

A structured approach for the organisation of staff for the performance of official controls was in place within the Environmental Health Service Wicklow local area. The Wicklow local area is currently responsible for carrying out official controls in five approved establishments. A new application for approval has been received from a food business operator that is to commence operating in the near future. The PEHO has re-organised the team and in 2017, official controls in the approved establishments will be carried out by two EHOs who will have responsibility for conducting the inspections in all of the currently approved establishments.

EHOs were authorised as required and warrants have been issued. One warrant was verified.

#### Coordination and Planning

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.

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls in approved establishments in Wicklow. The EHIS is used to schedule future inspections and also to monitor progress on planned activities. The PEHO carries out quarterly reviews on the EHIS and generates a list of establishments that fall behind the assigned inspection frequency.

#### Prioritisation of Official Controls and Risk Categorisation

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 operators, the reliability of own checks and any additional information on non-compliance.

3(2) Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an *ad hoc* basis.



File review by the audit team included an assessment of the information relating to the risk assessment for the approved establishments in Wicklow. Each of the approved establishments in Wicklow had been risk assessed and had a risk category assigned to them (all Category 1).

The inspection target set for approved establishments is two planned inspections per annum. During the review of the inspections on the EHIS for the five approved establishments, it was noted that all of the approved establishments received two inspections per annum, in 2015 and 2016, as a minimum. Where non-compliances had been noted on official control inspections, additional inspections were carried out, as appropriate.

Each local area has a Priority Action List to ensure that businesses which potentially pose a more immediate risk to public health, receive on-going attention. None of the approved establishments in the Wicklow local area were of a standard to warrant placement on the priority action list, at the time of this audit.

Inspections of approved establishments are unannounced (with the exception of advisory visits or inspections where specific persons or information are required to be present).

### 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 and must keep these procedures up-to-date.**

**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.**

The Environmental Health Service has documented a suite of national protocols, for use by the EHOs in carrying out official controls. The following Environmental Health Service protocols were relevant to this audit:

- Protocol 2 853 Registration and Approval
- Protocol 3 Inspection of a Food Business
- Protocol 4 Food Complaints
- Protocol 5 Food Business Complaints
- Protocol 8 Food Sampling
- Protocol 9 Food Alerts
- Protocol 11 Food Enforcement Procedure

The staff confirmed that these protocols are used in carrying out official controls and there was evidence on the files of use of these protocols and the related records.

### Identification, Follow-up and Close-out of Non-compliances

**Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies 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 with regard to non-compliance.**

**Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed.**

The review of the approved establishment files confirmed that when non-compliances with food law are identified during official control inspections, the food business operator is notified and follow-up action is taken as appropriate. The records relating to subsequent inspections provided evidence that non-compliances are assessed for close-out during the next inspection. In the two plants visited as part of the on-site verification, it was evident that when non-compliances are identified during official control inspections, there is prompt communication of the non-compliances with food law to the food business operators.

Enforcement action may include the following: Improvement Notice, Improvement Order, Prohibition Order, Closure Order or Prosecution. There has been one Improvement Notice served in relation to one of the approved establishments supervised by the Environmental Health Service in Wicklow in 2014.

### Reports to Food Business Operators

**Article 9 of Regulation (EC) No 882/2004 requires that competent authorities 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.**

It was noted during the file review that reports are sent to the food business operators following on-site inspections when non-compliances are identified, as per the national protocol. These reports specified the non-compliances identified and in some cases, the timeframe for the implementation of corrective action.

### Verification and Review of Official Controls and Procedures

**Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.**

**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 the 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.**

At the time of the audit, systems to verify the effectiveness of official controls were in place in the Environmental Health Service in Wicklow. The SEHO carries out a review of two food business operator files per EHO on an annual basis to verify that official controls were being carried out in a consistent manner. At the time of this audit, none of the approved establishments had been the subject of this review process.

Discussions take place at staff meetings with regards to items of interest that an EHO may have dealt with, in addition, the EHO can consult immediately with the SEHO or PEHO on any topic which they wish to discuss.

### Staff Performing Official Controls

**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.**

The EHOs in the Wicklow local area were very knowledgeable of the requirements of national and EU legislation requirements and also with GN1 and Environmental Health Service protocols. Training in local areas of the Environmental Health Service is facilitated through a national training plan which is developed annually.

The two EHOs that will be responsible for undertaking official controls in the approved establishments recently attended shelf-life training, as well as other training relevant to the supervision of approved establishments. Online training relating to microbiological criteria was carried out as part of a team meeting, to ensure consistency of application. When EHOs attend training, they provide feedback on that topic at the local area staff meetings which may take the format of discussions and presentations. Information from training sessions (presentations, etc.) is held on a shared drive, to which all staff have access.

### Registration and Approval

**Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments. In addition, it requires competent authorities to draw up and keep up-to-date a list of food business operators which have been registered.**

**Article 3 of Regulation (EC) No 854/2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation 882. In addition, Article 3(3) states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.**

At the time of this audit, there were five approved establishments under the supervision of the Environmental Health Service in Wicklow, which were approved between 2009 and 2012. Evidence of the approval process is maintained on an approval file and was provided for each of the establishments. The issuing of approval certificates to food business operators was prompt following the approval inspection. One establishment received conditional approval and subsequent to this, received full approval.

No application for approval had been refused and no approvals had been suspended or restricted, at the time of the audit. Two approvals had been revoked in Wicklow by the Environmental Health Service, in one case due to the closure of the establishment and in the other case, due to a change in the activities being undertaken by the food business operator. At the time of this audit, an application for approval had been recently received from a new food business operator.

Three amendments to approval certificates were issued since the issuing of the original approval certificates.

One of the establishments selected for on-site verification was not approved for porcine species however, it was processing pork, and stated that this had been part of its product range for a number of years.

## Service Contract Requirements

### 2.2.2.2 Food establishments subject to approval under Regulation (EC) No 853/2004

**Official controls of food businesses subject to under Regulation (EC) No. 853/2004 must be carried out in line with the Authority guidance on approvals under Regulation (EC) No 853/2004 of establishments supervised by the HSE consistent with similar/equivalent official controls carried out by other official agencies, as coordinated through the Authority.**

The approvals of the five establishments had been carried out between 2009 and 2012. Records of the approvals applications, approval recommendations from the PEHO and notification to the FSAI for approval number and copies of certificates, were maintained on a file for each of the approved establishments.

**The official agency shall grant/withdraw/suspend/amend the approval in accordance with the provisions of food legislation, the Authority's guidance and official agency procedures. The official agency shall notify the Authority without delay of changes to establishment approvals to facilitate publication of an up-to-date list on the Authority's website.**

The information relating to approved establishments and their approval is maintained in the EHIS. Changes to the status of the approval are notified to the RCEHO, the national office and the FSAI. Evidence of notification to the FSAI (for the purposes of updating the national list of approved establishments under the supervision of the HSE) of amendments to approvals, was maintained on the files for the relevant approved establishments.

**Approved establishments must be risk categorised to determine the frequency of inspection in accordance with legislative requirements. The Authority will be consulted in advance of any national planned change to the frequency of inspections in Guidance Note No.1.**

**Inspections must be carried out in accordance with legislative requirements, the Authority guidance and Official Agency procedures. The inspection process should be carried out in accordance with the Authority's Guidance Note No. 1. The official agency shall keep the approval of establishments under review when carrying out official controls.**

Evidence of risk categorisation was provided during the review of the files for the approved establishments. The Regulation 853 visit record sheet includes a prompt for the EHO to review the approval status during official control inspections.

## 4.4. Audit Findings ~ Local Area Fingal

### Organisation and Structure of Official Controls

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.

Article 4(2) The competent authorities shall ensure: that

- They have, or have access to, an adequate laboratory capacity for testing
- A sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively
- Appropriate and properly maintained equipment and facilities
- Legal powers to carry out official controls

A structured approach for the organisation of staff for the performance of official controls was in place within the Environmental Health Service local area in Fingal. The Fingal local area is currently responsible for carrying out official controls in one approved establishment. Official controls in the approved establishment are conducted by two EHOs.

EHOs were authorised as required and warrants have been issued. The warrants for the EHOs carrying out official controls in the approved establishment were verified.

### Coordination and Planning

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.

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls in the approved establishment in the Fingal local area. The EHIS is used to plan future inspections and also to monitor progress on planned inspections. The PEHO discusses the outcomes of any official controls which take place in the approved establishment with the EHOs following the inspections.

### Prioritisation of Official Controls and Risk Categorisation

3(2) Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an *ad hoc* basis.

File review by the audit team included an assessment of the information relating to the risk assessment for the approved establishment. The approved establishment had been risk assessed and had a Risk Category 1 assigned to it as per GN 1.

The inspection target set for approved establishments is two planned inspections per annum. During the review of the inspections for the approved establishment, it was noted that it had received two planned surveillance inspections in 2015, as well as an inspection relating to a food incident. The EHOs indicated that due to the size and complexity of the establishment, while inspections were lengthy and thorough, that they would not meet all of the criteria of an 853 planned inspection; and so were recorded as an 853 surveillance inspection. In 2016, the approved establishment received two 853 planned inspections.

The EHOs carrying out official controls in the approved establishment had adopted a more formal audit approach, whereby assessment of the food business operator's procedures and records was undertaken in advance of and post inspection. Evidence of this detailed analysis of the food business operator's documentation was maintained on files by the EHOs, including follow-up on queries and clarifications.

In line with the audit approach adopted in relation to this approved establishment, official controls are notified to the food business operator in some cases. In 2015 and 2016, one inspection was not announced to the food business operator. The Environmental Health Service indicated that this was necessary to allow for assessment of paperwork prior to inspection, and also to ensure that the food business operator's Food Safety Manager was available to facilitate the inspection.

Where non-compliances had been noted on official control inspections, these were notified to the food business operator.

Each local area has a Priority Action List to ensure that businesses that potentially pose a more immediate risk to public health, receive on-going attention. The approved establishment in the Fingal local area was not of a standard to warrant placement on the priority action list at the time of this audit.

### 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 and must keep these procedures up-to-date.**

**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.**

The Environmental Health Service has documented a suite of national protocols for use by EHOs in carrying out official controls. The following Environmental Health Service protocols were relevant to this audit:

- Protocol 2 853 Registration and Approval
- Protocol 3 Inspection of a Food Business
- Protocol 4 Food Complaints
- Protocol 5 Food Business Complaints
- Protocol 8 Food Sampling
- Protocol 9 Food Alerts
- Protocol 11 Food Enforcement Procedure

The staff confirmed that these protocols are used in carrying out official controls and there was evidence on the files of use of these protocols and the related records. However, the visit record maintained as part of the hard copy file was in three out of four cases an 852 visit record, rather than an 853 visit record. However, the EHOs were very familiar with the additional requirements for an 853 approval inspection and had covered these (identification mark on packaging, temperatures for minced meat, sourcing from approved suppliers only) during inspections.

### Identification, Follow-up and Close-out of Non-compliances

**Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies 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 with regard to non-compliance.**

**Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed.**

The review of the approved establishment file confirmed that when non-compliances with food law are identified during official control inspections, the food business operator is notified and follow-up action is taken by the inspector as appropriate. The records relating to subsequent inspections provided evidence that non-compliances are assessed for close-out by the EHOs during the next inspection. In the approved establishment visited as part of the onsite verification, it was evident that when non-compliances are identified during official control inspections, extensive follow-up and communication are undertaken by the EHOs.

Enforcement action may include the following: Improvement Notice, Improvement Order, Prohibition Order, Closure Order or Prosecution. At the time of this audit, no enforcement action had been required in the approved establishment in the Fingal local area.

### Reports to Food Business Operators

**Article 9 of Regulation (EC) No 882/2004 requires that competent authorities 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.**

It was noted during the file review, that reports are sent to the food business operator following on-site inspections when non-compliances are identified, as per the national protocol. These reports specified the non-compliances identified and the requirement for corrective action to be carried out by the food business operator.

### Verification and Review of Official Controls and Procedures

**Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.**

**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 the 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.**

At the time of the audit, systems to verify the effectiveness of official controls carried out in the approved establishment were in place. As there is only one approved establishment under the supervision of the Environmental Health Service in Fingal local area, the official controls being carried out are kept under review by the PEHO and the EHOs usually discuss any issues that arise as well as inspection outcomes, with the PEHO.

### Staff Performing Official Controls

**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.**

The audit team found the staff to be very knowledgeable of the requirements of national and EU legislation requirements and also with GN1 and Environmental Health Service protocols. Training in local areas is facilitated through a national training plan which is developed annually.

The EHOs who carry out official controls in the approved establishment have attended training relating to auditing ('Better Training for Safer Food' course) and Regulation (EC) No 2073/2005 on microbiological criteria. Feedback is provided at local area staff meetings regarding topics which have implications for other EHOs, e.g. updates were provided at staff meetings regarding Regulation (EC) No 2073/2005, outbreak management and high-pressure processing.

### Registration and Approval

**Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments. In addition, it requires competent authorities to draw up and keep-up-to-date, a list of food business operators which have been registered.**

**Article 3 of Regulation (EC) No 854/2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation 882. In addition, Article 3(3) states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.**

At the time of this audit, there was one approved establishment in the Fingal local area which was approved in 2010. Evidence of the approval process was maintained by the EHOs on file. The establishment received



conditional approval and subsequent to this, received full approval. The application for approval by the food business operator was for 'not ready-to-eat' but the notification to the FSAI for approval was for 'ready-to-eat'. The approval certificates issued (both first and second conditional and full approvals) indicate approval is for 'not ready-to-eat'. The approval for this establishment was amended in 2014 to reflect a change in the food business operator's activities which was identified by the Environmental Health Service during official controls.

No application for approval had been refused and no approvals had been suspended or restricted, at the time of the audit in the Fingal local area.

### Service Contract requirements

#### 2.2.2.2 Food establishments subject to approval under Regulation (EC) No 853/2004

**Official controls of food businesses subject to under Regulation (EC) No 853/2004 must be carried out in line with the Authority guidance on approvals under Regulation (EC) No 853/2004 of establishments supervised by HSE consistent with similar/equivalent official controls carried out by other official agencies, as coordinated through the Authority.**

Records of the approval application, approval recommendation from PEHO and notification to the FSAI for approval number as well as approval certificate (and amendment thereof) were maintained on file for the approved establishments.

**The official agency shall grant/withdraw/suspend/amend the approval in accordance with the provisions of food legislation, the Authority's guidance and official agency procedures. The official agency shall notify the Authority without delay of changes to establishment approvals to facilitate publication of an up-to-date list on the Authority's website.**

The information relating to the approved establishment and the approval is maintained in the EHIS and also in hard copy files. Changes to the status of the approval are notified to the RCEHO, the national office and the FSAI. Evidence of notification to the FSAI (for the purposes of updating the national list of approved establishments under the supervision of the HSE) of amendments to approvals, were maintained on the file for the approved establishment.

**Approved establishments must be risk categorised to determine the frequency of inspection in accordance with legislative requirements. The Authority will be consulted in advance of any national planned change to the frequency of inspections in Guidance Note No.1.**

**Inspections must be carried out in accordance with legislative requirements, the Authority guidance and official agency procedures. The inspection process should be carried out in accordance with the Authority's Guidance Note No. 1. The official agency shall keep the approval of establishments under review when carrying out official controls.**

Evidence of risk categorisation was provided during the review of the file for the approved establishment. The EHOs indicated that the approval status of the establishment was reviewed during official control inspections.

## 4.5. Audit Findings ~ Local Area Clare

### Official Control Preliminary Findings

#### Organisation and Structure of Official Controls

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

**Article 4(2) The competent authorities shall ensure: that**

- They have, or have access to, an adequate laboratory capacity for testing
- A sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively
- Appropriate and properly maintained equipment and facilities
- Legal powers to carry out official controls

A structured approach for the organisation of staff for the performance of official controls was in place within the Environmental Health Service local area in Clare. The local area is currently responsible for carrying out official controls in three approved establishments. Official controls in the approved establishments are typically conducted by two EHOs.

EHOs were authorised as required and warrants have been issued. The warrants for the EHOs carrying out official controls in the approved establishments were verified.

#### Coordination and Planning

**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.**

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls in the approved establishments in the Clare local area. The EHIS is used to plan future inspections and also to monitor progress on planned activities. Twice yearly, there are individual meetings with each of the EHOs and the PEHO or SEHO, where review of work is undertaken. During these meetings, any issues that arise with regards to supervision of an establishment can be discussed. Any queries or issues that arise during official controls in approved establishments are discussed with the SEHO or PEHO, as appropriate.

### Prioritisation of Official Controls and Risk Categorisation

**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 operators, the reliability of own checks and any additional information on non-compliance.**

**3(2) Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an *ad hoc* basis.**

File review by the audit team included an assessment of the information relating to the risk assessment for the three approved establishments in the Clare local area. The approved establishments had been risk assessed and had a risk category assigned to them as per GN 1.

The inspection target set for approved establishments is two planned inspections per annum. During the review of the inspections for the approved establishments it was noted that the approved establishments received the inspections as per the target. One of the approved establishments is seasonal in nature.

Official control inspections of approved establishments are unannounced with the exception of advisory visits, or follow-up inspections where specific persons or information are required to be present. Where non-compliances had been noted on official control inspections, these were notified to the food business operator and additional inspections were carried out, as appropriate.

Each local area has a Priority Action List to ensure that businesses that potentially pose a more immediate risk to public health, receive on-going attention. None of the approved establishments in the Clare local area were of a standard to warrant placement on the priority action list at the time of this audit.

### 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 and must keep these procedures up-to-date.**

**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.**

The Environmental Health Service has documented a suite of national protocols, for use by EHOs in carrying out official controls. The following Environmental Health Service protocols were relevant to this audit:

- Protocol 2 853 Registration and Approval
- Protocol 3 Inspection of a Food Business
- Protocol 4 Food Complaints
- Protocol 5 Food Business Complaints
- Protocol 8 Food Sampling
- Protocol 9 Food Alerts
- Protocol 11 Food Enforcement Procedure

The Clare local area confirmed that these protocols are used in carrying out official controls and there was evidence on the files of use of these protocols and the related records. The EHOs were very familiar with the additional requirements for an 853 approval inspection and had covered these (identification mark on packaging, temperatures for minced meat, sourcing from approved suppliers only) during inspections.

### Identification, Follow-up and Close-out of Non-compliances

**Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies 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 with regard to non-compliance.**

**Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed.**

The review of the approved establishment files confirmed that when non-compliances with food law are identified during official control inspections, the food business operator is notified and follow-up action is taken by the inspector as appropriate. The records relating to subsequent inspections provided evidence that non-compliances are assessed for close-out by the EHOs during the next inspection.

Enforcement action may include the following: Improvement Notice, Improvement Order, Prohibition Order, Closure Order or Prosecution. At the time of this audit, no enforcement action had been required in any of the approved establishments in the Clare local area.

### Reports to Food Business Operators

**Article 9 of Regulation (EC) No 882/2004 requires that competent authorities 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.**

It was noted during the file review that reports are sent to the food business operators following on-site inspections when non-compliances are identified, as per the national protocol. These reports specified the non-compliances identified and the requirement for corrective action to be carried out by the food business operators.

### Verification and Review of Official Controls and Procedures

**Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.**

**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 the 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.**

At the time of the audit, systems to verify the effectiveness of official controls were in place in the Clare local area. The PEHO/SEHO carries out a one-to-one review of work carried out by EHOs on a twice yearly basis to verify that official controls were being carried out in a consistent manner.

The official controls being carried out in the approved establishments are kept under review by the PEHO and the EHOs discuss any issues that arise with the SEHO or the PEHO.

### Staff Performing Official Controls

**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.**

The audit team found the staff in the Clare local area to be very knowledgeable of the requirements of national and EU legislation requirements and also with GN1 and the relevant Environmental Health Service protocols. Training in local areas of the Environmental Health Service is facilitated through a national training plan which is developed annually.

The EHOs that carry out official controls in the approved establishments have attended: a regional shellfish event, training relating to Food Information to Consumers (FIC), Regulation (EC) No 2073/2005, VTEC, *Campylobacter*, shelf-life training and import controls,. Feedback is provided at local area staff meetings regarding matters of relevance for other EHOs and there was evidence of discussions regarding Regulation (EC) No 2073/2005 and Marginalised, Localised and Restricted (MLR).

### Registration and Approval

**Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments. In addition, it requires competent authorities to draw up and keep up to date a list of food business operators which have been registered.**

**Article 3 of Regulation (EC) No 854/2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation 882. In addition, Article 3(3) states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.**

At the time of this audit, there were three approved establishments in the Clare local area. Evidence of the approval process for each of the three approved establishments was maintained on file and was provided for each of the establishments. One of the establishments had received two conditional approvals and subsequent to this received full approval. Another of the approved establishments had received a conditional approval, which was still in place at the time of this audit. One of the approved establishments had recently undergone a review of its activities and the approval had been amended as a result of that review. The original approval certificate had been returned by the food business operator, and the amended certificate had been sent to the food business operator.

No application for approval had been refused and no approvals had been suspended or restricted at the time of the audit in the Clare local area.

### Service Contract requirements

#### 2.2.2.2 Food establishments subject to approval under Regulation (EC) No 853/2004

**Official controls of food businesses subject to under Regulation (EC) No 853/2004 must be carried out in line with the Authority guidance on approvals under Regulation (EC) No 853/2004 of establishments supervised by the HSE consistent with similar/equivalent official controls carried out by other official agencies, as coordinated through the Authority.**

Records of the approval applications, approval recommendations from PEHO and notification to the FSAI for approval number as well as approval certificates (and amendments thereof) were maintained on file for the approved establishments.

**The official agency shall grant/withdraw/suspend/amend the approval in accordance with the provisions of food legislation, the Authority's guidance and official agency procedures. The official agency shall notify the Authority without delay, of changes to establishment approvals to facilitate publication of an up-to-date list on the Authority's website.**

The information relating to approved establishments and their approval is maintained in the EHIS and also in hard copy files. Changes to the status of the approval are notified to the RCEHO, the national office and the FSAI. Evidence of notification to the FSAI (for the purposes of updating the national list of approved establishments under the supervision of the HSE) of amendments to approvals, was maintained on the file for the approved establishments.

**Approved establishments must be risk categorised to determine the frequency of inspection in accordance with legislative requirements. The Authority will be consulted in advance of any national planned change to the frequency of inspections in Guidance Note No.1.**

**Inspections must be carried out in accordance with legislative requirements, the Authority guidance and Official Agency procedures. The inspection process should be carried out in accordance with the Authority's Guidance Note No. 1. The official agency shall keep the approval of establishments under review when carrying out official controls.**

Evidence of risk categorisation was provided during the review of the file for the approved establishments. The EHOs indicated that the approval status of the establishments was reviewed during official control inspections and evidence of this was maintained on the establishment files.

## 4.6. Audit Findings ~ Local Area Wexford

### Official Control Preliminary Findings

#### Organisation and Structure of Official Controls

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.

Article 4(2) The competent authorities shall ensure: that

- They have, or have access to, an adequate laboratory capacity for testing
- A sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively
- Appropriate and properly maintained equipment and facilities
- Legal powers to carry out official controls

A structured approach for the organisation of staff for the performance of official controls was in place within the Environmental Health Services in Wexford. The Wexford local area is currently responsible for carrying out official controls in one approved establishment. A second food business operator had secured an establishment and had been approved in August, 2015 however, it had not been operational since January, 2016. The food business operator requested that the approval remain in place in the hopes that it would re-commence activities. However, this did not happen and the Environmental Health Service commenced the revocation process in January, 2017.

EHOs were authorised as required and warrants have been issued. The warrants for the EHOs carrying out official controls in the approved establishment were verified.

#### Coordination and Planning

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.

The audit team confirmed that there was a structured and well organised approach for the coordination and planning of official controls in the approved establishment in the Wexford local area. The EHIS is used to plan future inspections and also to monitor progress on planned inspections. The biannual review of files with the PEHO and EHOs is planned to commence in April, following the recent appointment of the PEHO.

#### Prioritisation of Official Controls and Risk Categorisation

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 operators, the reliability of own checks and any additional information on non-compliance.

**3(2) Official controls shall be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad hoc basis.**

File review by the audit team included an examination of the information relating to the risk assessment for the two approved establishments. The approved establishments had been risk assessed and had a risk category assigned to them as per GN 1.

The inspection target set for approved establishments is two planned inspections per annum. During the review of the inspections for the operational approved establishment, it was noted that it received one planned inspection and one planned surveillance inspection in 2015. The EHOs indicated that due to the nature of food businesses, if the food business operator was not present while inspections were being conducted, access to all records and paperwork was not always possible. This meant that the inspection would not meet all of the criteria of an 853 planned inspection and so were recorded as an 853 surveillance inspection. In 2016, the approved establishment received one planned inspection and one surveillance inspection. In 2017, there was a planned inspection. All official control inspections at this establishment were unannounced.

The official controls in the approved establishment were a mix of single EHO inspections and joint inspections with a SEHO.

Where non-compliances had been noted on official control inspections, these were notified to the food business operator.

Each Environmental Health Service area has a Priority Action List to ensure that businesses that potentially pose a more immediate risk to public health, receive on-going attention. None of the approved establishments in the Wexford local area were of a standard to warrant placement on the priority action list, at the time of this audit.

### 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 and must keep these procedures up-to-date.**

**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.**

The Environmental Health Service has documented a suite of national protocols for use by EHOs in carrying out official controls. The following Environmental Health Service protocols were relevant to this audit:

- Protocol 2 853 Registration and Approval
- Protocol 3 Inspection of a Food Business
- Protocol 4 Food Complaints
- Protocol 5 Food Business Complaints
- Protocol 8 Food Sampling
- Protocol 9 Food Alerts
- Protocol 11 Food Enforcement Procedure



The staff confirmed that these protocols are used in carrying out official controls and there was evidence on the files of use of these protocols and the related records. The EHOs were very familiar with the additional requirements for an 853 approval inspection and had covered these (identification mark on packaging, temperatures for minced meat, sourcing from approved suppliers only) during inspections.

### Identification, Follow-up and Close-out of Non-compliances

**Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies 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 with regard to non-compliance.**

**Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed.**

The review of the approved establishment file confirmed that when non-compliances with food law are identified during official control inspections the food business operator is notified and follow-up action is taken by the Environmental Health Service as appropriate. The records relating to subsequent inspections provided evidence that non-compliances are assessed for close-out by the EHOs during the next inspection.

Enforcement action may include the following: Improvement Notice, Improvement Order, Prohibition Order, Closure Order or Prosecution. At the time of this audit, no enforcement action had been required in either of the approved establishments in the Wexford local area.

### Reports to Food Business Operators

**Article 9 of Regulation (EC) No 882/2004 requires that competent authorities 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.**

It was noted during the file review, that reports are sent to the food business operator following on-site inspections when non-compliances are identified, as per the national protocol. These reports specified the non-compliances identified and the requirement for corrective action to be carried out by the food business operator.

### Verification and Review of Official Controls and Procedures

**Article 4(2)(a) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the effectiveness and appropriateness of official controls.**

**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 the 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.**

At the time of the audit, systems to verify the effectiveness of official controls carried out in the approved establishment were in place. The biannual file reviews are planned to commence in April, following the recent appointment of the PEHO. As there is only one approved establishment under the supervision of the Environmental Health Service in Wexford, the official controls being carried out are kept under review and there is open communication regarding any issues that arise as well as inspection outcomes between the EHOs and the SEHO/PEHO.

### Staff Performing Official Controls

**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.**

The audit team found the staff to be very knowledgeable of the requirements of national and EU legislation requirements and also with GN1 and Environmental Health Service protocols. Training in local areas is facilitated through a national training plan which is developed annually.

The EHOs that carry out official controls in the approved establishment have attended training relating to Regulation (EC) No 2073/2005, allergens, nutritional labeling, FIC, *listeria* as well as having attended training days where presentations on 853 and MLR were provided. Feedback is provided at the local area staff meetings regarding topics which may have implications for other EHOs, e.g. updates were provided at staff meetings regarding additives, inspection frequency and risk profiling of 853 establishments.

### Registration and Approval

**Article 31 of Regulation (EC) No 882/2004 requires competent authorities to establish procedures for food business operators to follow when applying for the registration of their establishments. In addition, it requires competent authorities to draw up and keep up-to-date a list of food business operators which have been registered.**

**Article 3 of Regulation (EC) No 854/2004 requires competent authorities to approve establishments in accordance with Article 31 of Regulation 882. In addition, Article 3(3) states that a competent authority shall give an approval number to establishments manufacturing food of animal origin.**

At the time of this audit, there was one approved establishment in the Wexford local area which was operational. A second food business operator had secured an establishment and had been approved in August, 2015 however, it had not been operational since January, 2016. The food business operator requested that the approval remain in place in the hopes that activities would re-commence. However, this did not happen and the Environmental Health Service commenced the revocation process in January, 2017.

The two establishments had been approved in 2010 and 2015 respectively. Evidence of the approval process was maintained on the establishments' files. The SEHO conducted a review of the activities for the approved establishment in 2013. A condition has been attached to this approval regarding notification and prior approval being required for any significant change to the nature and extent of the business, as detailed on the application.

A condition had been applied to the approval of the establishment that had stopped operating, which limited the quantities being produced by that food business operator.

No application for approval had been refused and no approvals had been suspended or restricted at the time of the audit in the Wexford local area.

### Service Contract requirements

#### 2.2.2.2 Food establishments subject to approval under Regulation (EC) No 853/2004

**Official controls of food businesses subject to under Regulation (EC) No 853/2004 must be carried out in line with the Authority guidance on approvals under Regulation (EC) No 853/2004 of establishments supervised by HSE consistent with similar/equivalent official controls carried out by other official agencies, as coordinated through the Authority.**

Records of the approval application, approval recommendation from PEHO and notification to the FSAI for approval number as well as approval certificate, were maintained on file for the approved establishments.

**The official agency shall grant/withdraw/suspend/amend the approval in accordance with the provisions of food legislation, the Authority's guidance and official agency procedures. The official agency shall notify the Authority without delay, of changes to establishment approvals to facilitate publication of an up to date list on the Authority's website.**

The information relating to the approved establishment and the approval is maintained in the EHIS and also in hard copy files. Changes to the status of the approval are notified to the RCEHO, the national office and the FSAI. Evidence of notification to the FSAI (for the purposes of updating the national list of approved establishments under the supervision of the HSE) was maintained on the file for the approved establishment.

**Approved establishments must be risk categorised to determine the frequency of inspection in accordance with legislative requirements. The Authority will be consulted in advance of any national planned change to the frequency of inspections in Guidance Note No.1.**

**Inspections must be carried out in accordance with legislative requirements, the Authority guidance and Official Agency procedures. The inspection process should be carried out in accordance with the Authority's Guidance Note No. 1. The official agency shall keep the approval of establishments under review when carrying out official controls.**

Evidence of risk categorisation was provided during the review of the file for the approved establishment. The EHOs indicated that the approval status of the establishment was reviewed during official control inspections and evidence of this was maintained on the establishment files.

## 5. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION

Audit findings requiring corrective action are listed in the corrective action plan. The findings identified during this audit should be disseminated nationally to ensure that corrective actions and opportunities for improvement identified are implemented across all regions.

[Click here to download the corrective action plan.](#)



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